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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
----------X
GOVERNMENT EMPLOYEES INSURANCE COMPANY, GEICO INDEMNITY COMPANY, GEICO GENERAL INSURANCE COMPANY and GEICO CASUALTY COMPANY,

Plaintiffs,

-against-

DIRECT RX PHARMACY INC. D/B/A SHARONAS PHARMACY,
RAFO YAGUDA A/K/A RAFAIL YAGUDAYEV,
ROBERT YAKUTILOV,
RICHARD JAY APPLE, M.D.,
RAFAEL ANTONIO DELACRUZ-GOMEZ, M.D.,
JEAN-PIERRE GEORGES BARAKAT, M.D. AND
JOHN DOE NOS. "1" THROUGH "5,"

Defendants.
----------X

Docket No.: _____( )

Plaintiffs Demand a Trial by Jury

COMPLAINT

Plaintiffs Government Employees Insurance Company, GEICO Indemnity Company, GEICO General Insurance Company and GEICO Casualty Company (collectively, "GEICO" or "Plaintiffs"), as and for their Complaint against Defendants, Direct Rx Pharmacy, Inc. d/b/a

Sharonas Pharmacy, Rafo Yaguda a/k/a Rafael Yagudayev, Robert Yakutilov, Richard Jay Apple, M.D., Rafael Antonio Delacruz-Gomez, M.D., Jean-Pierre Georges Barakat, M.D., and John Doe Nos. "1" through "5" (collectively, "Defendants"), hereby allege as follows:

NATURE OF THE ACTION

1. This action seeks to terminate an on-going fraudulent scheme perpetrated against GEICO by Defendants who have exploited the New York "No-Fault" insurance system by submitting more than $2,623,183.00 in fraudulent pharmaceutical billing to GEICO. The fraudulent scheme is spearheaded by Rafo Yaguda a/k/a Rafael Yagudayev ("Yaguda") and Robert Yakutilov ("Yakutilov") who use Direct Rx Pharmacy Inc. ("Direct Rx") to submit thousands of fraudulent No-Fault insurance charges using the United States mail seeking payment for a multitude of medically unnecessary and illusory "pain relieving" prescription drug products including, topical compounded pain creams, topical pain gels, lotions and ointments, and topical pain patches (collectively, the "Fraudulent Pain Products") allegedly dispensed to individuals involved in automobile accidents and eligible for insurance coverage under policies of insurance issued by GEICO ("Insureds"), in order to exploit the Insureds for financial gain.

2. As an essential part of this fraudulent scheme, Direct Rx, its alleged owner, Yaguda, and its former supervising pharmacist, Yakutilov (collectively, the "Pharmacy Defendants"), engage in illegal, collusive agreements with various prescribing health care providers, including Defendants Richard Jay Apple, M.D. ("Dr. Apple), Rafael Antonio Delacruz-Gomez, M.D. ("Dr. Delacruz-Gomez"), and Jean-Pierre Georges Barakat, M.D. ("Dr. Barakat") (collectively, the "Prescribing Defendants") who – without regard for genuine patient care – generate boilerplate, formulaic, illusory and/or medically unnecessary prescriptions for a multitude of pharmaceuticals, often using preprinted labels or rubber stamps generated and supplied to them by the Pharmacy Defendants in violation of law.

3. As a further part of the fraudulent scheme, Direct Rx engages in mass production and dispensing of set formulations of topical compounded pain creams (the "Fraudulent Compounded Pain Creams"), which are not approved by the United States Food and Drug Administration ("FDA"), without tailoring the medications to the individual needs of any individual patient, and without complying with state and federal licensing requirements designed to ensure the quality, safety and effectiveness of mass produced drug products. To disguise the violation of law, the Pharmacy Defendants present Direct Rx as a storefront neighborhood pharmacy in Richmond Hill, New York, when in fact it produces the Fraudulent Compounded Pain Creams in bulk by assembling combinations of multiple drug ingredients with unproven effects in order to create exorbitantly-priced products to financially enrich themselves rather than to treat or otherwise benefit the Insureds who purportedly receive them.

4. The scheme by the Pharmacy Defendants and the Prescribing Defendants to routinely prescribe and dispense to patients large volumes of the Fraudulent Pain Products pursuant to their collusive arrangements egregiously inflated the charges submitted to GEICO. For example, billing from the Pharmacy Defendants typically ranges from $923.10 to $1,493.54 for a single tube of the Fraudulent Compounded Pain Cream. Similarly, the Pharmacy Defendants dispense and bill for various non-prescription items, such as Terocin 4% patches at an average charge of $1,410.30 for a box of ten, which are available for purchase without a prescription at a fraction of that price.

5. The Defendants' scheme not only inflates the charges to insurers, but also poses serious risks to the patients' health, safety and well-being. For example, risks from diclofenac sodium – a product repeatedly prescribed and dispensed by the Defendants – include gastrointestinal side effects, as well as increased risk of major cardiovascular events, such as a

heart attack and stroke, while toxicity from the use of compounded pain creams can cause illness and, in extreme cases, even death.

6. By this action, GEICO seeks to recover at least $548,369.00 that was stolen from it by virtue of Defendants' fraudulent scheme, which damages are to be trebled under 18 U.S.C. § 1962(c), *et al.* to $1,645,107.00, along with a declaration that GEICO is not legally obligated to pay reimbursement to Direct Rx for more than $1,590,338.00 in pending fraudulent No-Fault claims the Defendants submitted or caused to be submitted through Direct Rx because:

(i) the billed-for pharmaceutical products were prescribed and dispensed pursuant to predetermined fraudulent protocols designed to exploit the patients for financial gain, without regard for genuine patient care;

(ii) the Defendants participated in illegal, collusive relationships in which the Pharmacy Defendants solicited and received illegal prescriptions from the Prescribing Defendants for Fraudulent Pain Products in exchange for unlawful kickbacks and other financial incentives;

(iii) the Defendants made and continue to make false and fraudulent misrepresentations to GEICO by submitting or causing to be submitted charges for the Fraudulent Pain Products pursuant to illegal, invalid, duplicitous and formulaic prescriptions; and

(iv) Direct Rx engaged in illegal bulk compounding by specializing in producing and dispensing large quantities of the Fraudulent Compounded Pain Creams in set formulations, in violation of Federal and New York State regulatory and licensing requirements imposed on pharmacies, drug manufacturers and outsourcing facilities, rendering it ineligible to receive reimbursement for No-Fault Benefits.

7. The Defendants fall into the following categories:

(i) Direct Rx is a New York corporation engaged in a fraudulent scheme in which it dispenses the Fraudulent Pain Products, including large volumes of the Fraudulent Compounded Pain Creams, pursuant to predetermined protocols, without regard to genuine patient care, in order to submit to GEICO and other New York automobile insurers claims for reimbursement of No-Fault Benefits to which it is not entitled;

(ii) Yaguda is the purported owner of Direct Rx;

(iii) Yakutilov is the former supervising pharmacist of Direct Rx;

(iv) The Prescribing Defendants are physicians and physician assistants who routinely prescribe or purport to prescribe the Fraudulent Pain Products in exchange for financial kickbacks and other financial incentives from the Pharmacy Defendants, and who engage in collusive arrangements with the Pharmacy Defendants whereby they prescribe, or purport to prescribe the Fraudulent Pain Products, including the Fraudulent Compounded Pain Creams; and

(v) John Doe Nos. "1" through "5" are persons and entities, presently not identifiable, who along with the Pharmacy Defendants, participate in the operation and control of Direct Rx, including facilitating the illegal, collusive relationships with the prescribing healthcare providers.

8. The Defendants' scheme began in 2013 and continues uninterrupted to the present day. As discussed more fully below, the Defendants at all times have known that: (i) the billed-for pharmaceuticals are prescribed and dispensed pursuant to predetermined fraudulent protocols designed to exploit the patients for financial gains, without regard for genuine patient care; (ii) the Defendants participate in illegal, collusive relationships in which the Pharmacy Defendants solicit and receive illegal prescriptions from the Prescribing Defendants for the Fraudulent Pain Products in exchange for unlawful kickbacks and other financial incentives; (iii) the Defendants make false and fraudulent misrepresentations to GEICO by submitting or causing to be submitted charges for the Fraudulent Pain Products pursuant to illegal, invalid, duplicitous and formulaic prescriptions; and (iv) Direct Rx engages in illegal bulk compounding by specializing in producing and dispensing large quantities of the Fraudulent Compounded Pain Creams in set formulations, in violation of Federal and New York State regulatory and licensing requirements.

9. Based on the foregoing, Direct Rx does not now have – and has never had – any right to be compensated for the Fraudulent Pain Products allegedly dispensed to GEICO insureds. The chart attached hereto as Exhibit "1" sets forth the fraudulent claims that have been identified to date which the Defendants submitted, or caused to be submitted, to GEICO through

United States mail. As a result of the Defendants' scheme, GEICO has incurred damages of approximately $548,369.00.

THE PARTIES

I. Plaintiffs

10. Plaintiffs Government Employees Insurance Company, GEICO Indemnity Company, GEICO General Insurance Company and GEICO Casualty Company are Maryland corporations with their principal places of business in Chevy Chase, Maryland. GEICO is authorized to conduct business and to issue automobile insurance policies in New York.

II. Defendants

11. Defendant Direct Rx is a New York corporation, incorporated on or about April 2, 2013, with its principal place of business at 102-05 Jamaica Avenue, Richmond Hill, New York.

12. Direct Rx, through the present day, knowingly has submitted fraudulent claims to GEICO and continues to seek reimbursement on unpaid fraudulent claims.

13. Direct Rx engages in pharmaceutical compounding activities and specializes in producing and dispensing compounded pain creams.

14. Direct Rx is registered with New York State as a pharmacy, but is not registered as a manufacturer or outsourcing facility.

15. Direct Rx is not permitted to engage in bulk compounding or to specialize in dispensing large quantities of compounded pain creams that are not specially tailored to the unique needs of individual patients.

16. The vast majority of the fraudulent claims submitted to Direct Rx to GEICO results from illegal, collusive agreements with the Prescribing Defendants named as defendants in this action; specifically, Dr. Apple, Dr. DelaCruz-Gomez, and Dr. Barakat, who work out of

various multidisciplinary medical clinics located in Queens, Staten Island and the Bronx that primarily treat No-Fault Patients (the "No-Fault Clinics").

17. Defendant Yaguda resides in and is a citizen of New Jersey. Yaguda is the owner of Direct Rx.

18. Defendant Yakutilov resides in and is a citizen of New York. Yakutilov is the former supervising pharmacist of Direct Rx.

19. Yakutilov was also the owner and supervising pharmacist of Direct Rx's predecessor, Avitz Rx Corp. d/b/a Sharonas Pharmacy ("Avitz Rx"), which also had a principal place of business at 102-05 Jamaica Avenue, Richmond Hill, New York.

20. Yakutilov incorporated Avitz Rx on or about May 8, 2012, and on or about May 7, 2013, Yakutilov entered into an agreement with Yaguda whereby Yakutilov purported to sell Avitz Rx to Yaguda. After the purported sale and transfer of the pharmacy to Yaguda, Yakutilov continued in his role of supervising pharmacist at Direct Rx.

21. Defendant Dr. Apple resides in and is a citizen of New York. Dr. Apple was licensed to practice medicine in New York on May 2, 1989.

22. Dr. Delacruz-Gomez resides in and is a citizen of New York. Dr. Delacruz-Gomez was licensed to practice medicine in New York on March 8, 1991.

23. Dr. Barakat resides in and is a citizen of New York. Dr. Barakat was licensed to practice medicine in New York on August 27, 2008.

24. John Doe Nos. 1 – 5 reside in and are citizens of New York. John Doe Nos. 1 – 5 are individuals and entities, presently not identifiable, who, along with the Pharmacy Defendants, participate in the operation and control of Direct Rx, including facilitating illegal, collusive relationships with the prescribing healthcare providers, whereby they prescribe, or purport to

prescribe, the Fraudulent Pain Products in exchange for financial kickbacks and other financial incentives from the Pharmacy Defendants.

JURISDICTION AND VENUE

25. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §1332(a)(1) because the matter in controversy exceeds the sum or value of $75,000.00, exclusive of interest and costs, and is between citizens of different states. Pursuant to 28 U.S.C. § 1331, this Court also has jurisdiction over the claims brought under 18 U.S.C. §§ 1961 et seq., the Racketeer Influenced and Corrupt Organizations ("RICO") Act, because they arise under the laws of the United States. In addition, this Court has supplemental jurisdiction over the subject matter of the claims asserted in this action pursuant to 28 U.S.C. § 1367.

26. Venue in this District is appropriate pursuant to 28 U.S.C. § 1391, as the Eastern District of New York is the District where one or more of the Defendants reside and because this is the District where a substantial amount of the activities forming the basis of the Complaint occurred.

ALLEGATIONS COMMON TO ALL CLAIMS

I. An Overview of New York's No-Fault Laws

27. GEICO underwrites automobile insurance in the State of New York.

28. New York's "No-Fault" laws are designed to ensure that injured victims of motor vehicle accidents have an efficient mechanism to pay for and receive the healthcare services that they need. Under New York's Comprehensive Motor Vehicle Insurance Reparations Act (N.Y. Ins. Law §§ 5101 et seq.) and the regulations promulgated pursuant thereto (11 N.Y.C.R.R. §§ 65 et seq.)(collectively, referred to herein as the "No-Fault Laws"), automobile insurers are required to provide Personal Injury Protection Benefits ("No-Fault Benefits") to Insureds.

29. No-Fault Benefits include up to $50,000.00 per Insured for necessary expenses that are incurred for health care goods and services.

30. An Insured can assign his or her right to No-Fault Benefits to the providers of healthcare services in exchange for those services. Pursuant to a duly executed assignment, a healthcare provider may submit claims directly to an insurance company and receive payment for necessary goods and medical services provided, using the claim form required by the New York State Department of Insurance (known as the "Verification of Treatment by Attending Physician or Other Provider of Health Service," or, more commonly, as an "NF-3"). In the alternative, healthcare providers sometimes submit claims using the Health Care Financing Administration insurance claim form (known as the "HCFA-1500 Form").

31. Pursuant to New York's No-Fault Laws (11 N.Y.C.R.R. § 65-3.16(a)(12)), a healthcare provider is not eligible to receive No-Fault Benefits if it fails to meet any applicable New York state or local licensing requirement necessary to perform such services in New York.

32. In State Farm Mut. Auto. Ins. Co. v. Mallela, 4 N.Y.3d 313 (2005), the New York Court of Appeals, relying on the implementing regulation, 11 N.Y.C.R.R. § 65-3.16(a)(12), made clear that healthcare providers that fail to comply with licensing requirements are ineligible to collect No-Fault benefits. The Court of Appeals further provided that insurers may look beyond a facially-valid license to determine whether there was a failure to abide by state and local law.

33. Pursuant to New York Insurance Law § 403, the NF-3s and HCFA-1500 Forms submitted by a healthcare provider to GEICO, and to all other automobile insurers, must be verified by the health care provider subject to the following warning:

> Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance or statement of claim containing

any materially false information, or conceals for the purpose of misleading, information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime.

II. An Overview of Applicable Licensing Requirements

34. New York Education Law § 6530(17) prohibits a physician from "exercising undue influence" on the patient by promoting the sale of drugs so as to exploit the patient for the financial gain of the licensee or of a third party.

35. New York Education Law § 6530(18) prohibits a physician from "directly or indirectly" offering, giving, soliciting, receiving or agreeing to receive any fee or other consideration to or from a third party in connection with the performance of professional services.

36. New York Education Law § 6509-a prohibits a professional licensee from "directly or indirectly" requesting, receiving, or participating in the division, transference, assignment, rebate, splitting, or refunding of a fee in connection with professional care or services related to drugs and/or medications.

37. New York Education Law § 6530(38) prohibits a licensed physician from entering into an arrangement or agreement with a pharmacy for the compounding and/or dispensing of coded or specially marked prescriptions, while New York Education Law § 6811 makes it a crime for any person to enter into an agreement with a physician (or other licensed healthcare provider) for the compounding or dispensing of secret formula ("coded") prescriptions.

38. New York Education Law § 6810 prohibits persons authorized to issue prescriptions for a drug from issuing prescriptions on a prescription form which provides for the dispensing or compounding of any other drug, and no drug shall be dispensed by a pharmacist when such prescription form includes any other drug.

39. New York Education Law § 6810 prohibits persons and corporations, not licensed to issue a prescription, to willfully cause prescriptions forms, blanks, or facsimiles thereof to be disseminated to any person other than a person who is licensed to issue a prescription.

III. An Overview of Compounded Drug Products

40. The United States Federal Food, Drugs, and Cosmetic Act ("FDCA") authorizes the United States Food and Drug Administration ('FDA") to oversee the safety of food, drugs, and cosmetics.

41. The FDA strictly regulates over-the-counter and prescription drugs, and oversees drug manufacturing in several ways, including testing drugs and routinely inspecting drug manufacturing plants and outsourcing facilities engaged in the compounding of drugs.

42. FDA-approved drugs require: (i) approval prior to marketing; (ii) compliance with federal labelling laws; and (iii) that the drugs be made and tested in accordance with good manufacturing practice regulations (GMPs), which are federal statutes that govern the production and testing of pharmaceutical products.

43. Pursuant to Section 503A of the Federal Food, Drug and Cosmetic Act ("FDCA"), as amended by the Compounding Quality Act, the laws applicable to drugs regulated by the FDA, including the laws relating to the safe manufacturing of drugs, generally do not apply to a "compounded" drug product: (1) if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order that a compounded product is necessary for the identified patient, and (2) if the compounding is performed by a licensed pharmacist in a state licensed pharmacy.

44. Compounded drugs are generally not FDA-approved, though they may include FDA-approved drugs, and are generally exempt from the FDA approval process which applies to new drugs if the drug is compounded for an identified individual patient based on the receipt of a

valid prescription, approved by the prescribing practitioner on the prescription order, that a compounded product is necessary for the identified patient. See 21 U.S.C. § 353a.

45. Unlike FDA-approved products, consumers and prescribers cannot assume that compounded drugs were made by validated processes in properly calibrated and cleaned equipment; that the ingredients in the drug were obtained from FDA-approved sources; that production personnel had the requisite knowledge and training; and that appropriate laboratory testing was performed to verify the compounded drug's potency, purity, and quality.

46. The FDA has publically expressed concern regarding large-scale drug manufacturing under the guise of traditional small-scale pharmacy compounding. For example, the FDA has noted that poor practices on the part of bulk drug compounders can result in contamination or products that do not possess the strength, quality, and purity required. Published reports also consistently show that compounded drugs fail to meet specifications at a considerably higher rate than FDA-approved drugs.

47. Traditional pharmacy compounding by state licensed pharmacies, therefore, is permissible when done on a small scale by pharmacists who prepare the medication based on an individual prescription. Specifically, when compounded drugs meet the requirements of 21 U.S.C. § 353a and are compounded for an individual patient, they can be exempted from the requirement, among others, that they be FDA-approved. See 21 U.S.C. § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to... this section is effective with respect to such drug").

48. When Congress adopted 21 U.S.C. § 353a, its express intent was to "ensure continued availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevent manufacturing [of drugs that would

otherwise require FDA approval] under the guise of compounding." H.R. Rep. No. 105-399, at 94 (1997) (Conf. Rep.)(emphasis added). As Congress stated at the time:

> the "exemptions in [this section] are limited to compounding for an individual patient based on the medical need of such patient for the particular drug compound. To qualify for the exemptions, the pharmacist or physician must be able to cite to a legitimate medical need for the compounded product that would explain why a commercially available drug product would not be appropriate. Although recording the medical need directly on each prescription order would not be required, this technique would be one of many acceptable ways of documenting the medical need for each compounded drug product. This medical need would not include compounding drugs that are essentially copies of commercially available drug products for largely economic reasons. The pharmacist may rely on appropriately documented input from the physician as to whether a commercially available drug product is not appropriate for the identified individual patient."

S. Rep. No. 105-43, at 67-68 (1997)(emphasis added).

49. The prescription of compounded drug products and ensuing billing to both private and public insurers has been the subject of state and federal investigations and litigation due to increased concerns regarding fraud.

50. The U.S. Department of Health & Human Services and the U.S. Postal Service have both issued reports documenting fraud concerns with compounded drugs. See *High Part D Spending on Opioids and Substantial Growth in Compound Drugs Raise Concerns*, HHS OIG Data Brief, OEI-16-00290 (June 2016); *Worker's Compensation Compound Drug Costs, Management Advisory,* Report No. HR-MA-16-003 (March 14, 2016). Most recently, the U.S. Department of Health issued a report which noted that many pharmacies in New York State are among the most questionable in the nation. See *Questionable Billing For Compounded Topical Drugs in Medicare Part D*, OEI-02-16-00440 (August 2018).

51. Further, there have been numerous criminal proceedings commenced connected to compounded drug products. For example:

- in January 2014, the United States Attorney for the District of New Jersey filed a criminal complaint against a pharmacist, who thereafter pled guilty, in connection with a fraudulent scheme involving payment of kickbacks in exchange for prescriptions for compounded pain creams. See USA v. Kleyman, 1:14-CR-598-JHR, Docket No. 1;

- in February 2016, the United States Attorney for the Northern District of Texas indicted two laypersons, who conspired with physicians and pharmacies, in a scheme involving producing, prescribing, and distributing compound creams, including payment of kickbacks to prescribing physicians and insured beneficiaries. See USA v. Cesario, 3:16-CR-060-M, Docket Nos. 3, 75;

- in June 2016, the United States Attorney for the Middle District of Florida indicted a physician who engaged in a fraudulent scheme involving payment of kickbacks for the referral of patients and prescriptions for compounded creams. See USA v. Baldizzi, 8:16CR271-MSS-AEP, Docket No. 1; and

- in August 2016, the United States Attorney for the Southern District of New York indicted more than 40 members of the Genovese, Gambino, Luchese, and Bonanno crime families, whose alleged illegal activities included "causing…corrupt doctors to issue unnecessary and excessive prescriptions for expensive compound cream" billed to insurers. See USA v. Parrello, 16 Crim. 522 (2016).

IV. The Defendants' Scheme Involving The Fraudulent Pain Products

A. Overview of the Scheme

52. Beginning in 2013, and continuing uninterrupted through the present day, the Pharmacy Defendants masterminded and implemented a fraudulent scheme in which they used Direct Rx to bill the New York automobile insurance industry for millions of dollars in inflated charges – which it was not eligible to receive – relating to the Fraudulent Pain Products purportedly provided to patients allegedly involved in automobile accidents.

53. As part of the Defendants' fraudulent scheme, in exchange for unlawful kickbacks or other compensation, the Prescribing Defendants purport to prescribe a multitude of prescription drugs (e.g., the Fraudulent Pain Products) to the Insureds, including medically unnecessary "pain relieving" prescription drug products including, primarily, topical

compounded pain creams (e.g., Fraudulent Compounded Pain Creams), topical pain gels, lotions and ointments (e.g., Diclofenac Sodium 3% Gel, Lidocaine Ointment and Terocin Lotion), and topical pain patches (e.g., Lidocaine 5% Patches and Terocin Patches) which in turn permits the Pharmacy Defendants to bill GEICO for the Fraudulent Pain Products through Direct Rx.

54. The Prescribing Defendants generate these duplicitous and invalid prescriptions at various multidisciplinary medical clinics that treat primarily No-Fault patients (the "No-Fault Clinics"), located in Queens, Staten Island and the Bronx, including clinics located at 90-04 Merrick Blvd., Jamaica, NY; 222-01 Hempstead Avenue, Queens Village, NY; 1655 Richmond Ave, Staten Island, NY; and 4014-A Boston Rd., Bronx, NY.

55. The No-Fault Clinics present themselves as legitimate healthcare practices when, in fact, they are one-stop-shop medical mills designed to subject Insureds to as many healthcare goods and services as possible in order to submit volumes of fraudulent claims to No-Fault insurers such as GEICO without regard to genuine patient care.

56. The Prescribing Defendants prescribe, and the Pharmacy Defendants dispense and bill for, the Fraudulent Pain Products knowing that (i) the Fraudulent Pain Products are prescribed and dispensed pursuant to predetermined protocols designed to exploit the patients for financial gain, without regard to genuine patient care or the availability of a wide range of commercially available, FDA-approved medications proven to have therapeutic effects available at a fraction of the cost; (ii) the Fraudulent Pain Products are the product of illegal, collusive agreements intended to inflate the billing to insurers and financially enrich the Defendants; (iii) the Fraudulent Pain Products often have no proven efficacy and/or are often duplicative of other medications contemporaneously prescribed to Insureds; and (iv) with respect to the Fraudulent

Compounded Pain Creams, they are almost never prescribed properly in accordance with the governing state and federal regulations.

57. In keeping with the fact that the Fraudulent Pain Products are prescribed pursuant to predetermined fraudulent protocols in order to financially enrich the Defendants, the Prescribing Defendants never give the Insureds the option to use a pharmacy of their choosing, rather the Prescribing Defendants direct the prescriptions for the Fraudulent Pain Products to Direct Rx in Richmond Hill, Queens, New York, regardless of the distance of this pharmacy from the Insureds or from the Prescribing Defendants.

B. The Fraudulent Pain Products are Prescribed and Dispensed Without Regard to Genuine Patient Care

58. In basic terms, the goal of medical treatment is to help patients get better in a timely manner. Notwithstanding this basic goal, the Insureds treated by the Prescribing Defendants are virtually always subjected to a predetermined and unnecessarily prolonged treatment protocol, which completely lacks in individualized care and fails to utilize evidence based medicine with the goal of the Insureds' timely return to good health.

59. Conversely, the treatment reports almost uniformly reflect that the Insureds treated by the Prescribing Defendants do not get better, do not return to good health, and/or do not experience improvement in their conditions such that the Insureds can terminate medical treatment expeditiously and return to normal activity.

60. As part of the predetermined protocol, the Prescribing Defendants produce generic, preprinted, and boilerplate examination reports designed to justify continued, voluminous and excessive healthcare services that the No-Fault Clinic providers purport to render to Insureds. These healthcare services include the prescription of excessive amounts of medically unnecessary pharmaceutical drug products such as the Fraudulent Pain Products.

61. Notwithstanding the creation of the examination reports, the Prescribing Defendants' prescriptions of the Fraudulent Pain Products are based on a predetermined protocol, designed to exploit the Insureds' for financial gain, without regard to the genuine needs of the patients.

62. To the extent any examination is actually performed at all, the Prescribing Defendants fail to document a detailed medical history of the patients to whom they prescribe the Fraudulent Pain Products. Prescribing a multitude of pharmaceutical drug products without first taking a detailed patient history demonstrates a gross indifference to patient health and safety as the Prescribing Defendants often do not know whether the patient is currently taking any medication or suffering from any co-morbidities that would contraindicate the use of a compounded drug product.

C. The Fraudulent Compounded Pain Cream Prescriptions

63. As part of their fraudulent, profit-driven scheme, the Defendants submit or cause to be submitted, millions of dollars in claims for medically unnecessary, ineffective Fraudulent Compounded Pain Creams.

64. Because compounded products are not FDA-approved, and therefore, not subject to FDA regulations regarding quality, safety and effectiveness of manufactured drug products, they should never be prescribed as a matter of routine therapy, and should only be prescribed to meet a legitimate specific need of an individual patient, or when all other forms of oral and/or topical medications approved for the treatment of pain have failed.

65. Prior to receiving a prescription for any compounded drug product, a patient's medical records should document all other forms of FDA-approved drugs that were prescribed and failed to treat the symptom for which the compounded drug product was then prescribed,

and/or the medical rationale that supports the otherwise premature prescription of a compounded drug product.

66. Direct Rx dispenses the Fraudulent Compounded Pain Creams, which are not FDA-approved, in pre-determined set formulations, without tailoring the medications to the individual needs of an individual patient, and without complying with licensing requirements that are designed to ensure the quality, safety and effectiveness of bulk compounded drug products.

67. Direct Rx, in order to generate profits, intentionally produces and dispenses the Fraudulent Compounded Pain Creams without regard for the absence of any proven efficacy of the combination of ingredients in a topical formulation.

68. In an effort to conceal this fraudulent scheme, Direct Rx produces and dispenses the Fraudulently Compounded Pain Creams while concomitantly dispensing commercially, available, FDA-approved medications including oral non-steroidal anti-inflammatory drugs ("NSAIDs") and other topical pain medications.

69. The Pharmacy Defendants then market these Fraudulent Compounded Pain Creams to various No-Fault Clinics that treat thousands of Insureds, and solicit the physicians operating therefrom, including the Prescribing Defendants, to prescribe the medically unnecessary and illusory Fraudulent Compounded Pain Creams to the Insureds. The Pharmacy Defendants then use those prescriptions to bill GEICO for the Fraudulent Compounded Pain Creams under the name of Direct Rx.

70. In furtherance of the scheme, the Pharmacy Defendants provide the prescribing physicians, including the Prescribing Defendants, with preprinted labels or rubber stamps which contain the names and the ingredients of the Fraudulent Compounded Pain Creams, including the

percentage concentrations of each ingredient used. The Pharmacy Defendants provide the prescribing physicians, including the Prescribing Defendants, with preprinted labels and rubber stamps in order to make it as convenient as possible for the prescribing physicians to authorize as many prescriptions as possible for the Fraudulent Compounded Pain Creams.

71. The Prescribing Defendants then use these preprinted labels or rubber stamps on their official New York State prescription pads to prescribe the Fraudulent Compounded Pain Creams to the Insureds, which are then created, produced and dispensed by the Pharmacy Defendants.

72. A representative sample of Direct Rx's bills and the accompanying prescriptions issued by the Prescribing Defendants using the preprinted labels or rubber stamps, and which the Defendants submitted or caused to be submitted to GEICO in support of their fraudulent billing, is annexed hereto as Exhibit "2".

73. The prescribing physicians often recommend Insureds continue taking oral NSAIDs (e.g., ibuprofen and naproxen) and/or prescribe oral NSAIDs contemporaneous to prescribing the Fraudulent Compounded Pain Creams, which is known as duplication of therapy. The simultaneous and combined use of oral NSAIDs and Fraudulent Compounded Pain Creams can cause adverse events to the patient and very often leads to emergency room visits because the use of more than one medication in the same class of drugs exacerbates the possible adverse side effects.

74. In keeping with the fact that the Fraudulent Compounded Pain Creams are prescribed and dispensed pursuant to the Defendants' fraudulent scheme, licensed physicians, including the Prescribing Defendants, often tailor their examination forms to include the

prescription and dispensing of the Fraudulent Compounded Pain Creams that are produced and dispensed by the Pharmacy Defendants.

75. For example, the treatment plan section of Dr. DelaCruz-Gomez's examination forms lists "compound" as a preprinted medication that is routinely prescribed to patients. Dr. DelaCruz-Gomez circles "compound" on every initial examination report for every patient for which he purportedly prescribes a Fraudulent Compounded Pain Cream. Then he or someone employed at the No-Fault Clinics from where he operates, handwrites the coded name of the Fraudulent Compounded Pain Cream that is to be prescribed to the patient. Dr. Delacruz-Gomez then prescribes the Fraudulent Compounded Pain Creams using a preprinted label or rubber stamp provided to him by the Pharmacy Defendants.

76. Notably, the prescription and dispensing of the Fraudulent Compounded Pain Creams and the respective examination reports are virtually never supplemented with an explanation as to why the compounded drug products are medically necessary for the unique needs of an individual Insured.

77. Moreover, the Prescribing Defendants' follow-up examination reports fail to explain whether the Fraudulent Compounded Pain Creams were effective and/or whether the patient experienced any side effects. In fact, the follow-up examination reports virtually never even reference the fact that a Fraudulent Compounded Pain Cream was prescribed to the patient.

78. Direct Rx uses these fraudulent prescriptions to bill GEICO and other insureds millions of dollars for the Fraudulent Pain Products, including the Fraudulent Compounded Pain Creams.

79. Direct Rx bills GEICO $923.10 to $1,493.54 for a single tube of the Fraudulent Compounded Pain Creams.

80. The Defendants submit these exorbitant charges knowing that the topical efficacy of the Fraudulent Compounded Pain Creams that Direct Rx produces and dispenses is unproven, and that there are a wide range of commercially available, FDA-approved medications proven to have therapeutic effects available at a fraction of the cost, claims which the Defendant are also submitting or causing to be submitted to GEICO.

81. Defendants know that there is no legitimate medical need for the Fraudulent Compounded Pain Creams that could explain why a commercially available drug product alone would not be appropriate for the patients who are instead prescribed and dispensed the exorbitantly-priced Fraudulent Compounded Pain Creams in addition to such commercially available products.

82. The Pharmacy Defendants, solely to maximize profits, had, and continue to have Direct Rx specialize in illegal compounding, producing large quantities of compounded drugs in set formulations, as part of the collusive agreements made with licensed physicians and their associates (i.e., the "Prescribing Defendants") to compound and dispense specially marked, formulaic prescriptions.

83. The Fraudulent Compounded Pain Creams produced by Direct Rx: (i) are not medically necessary; (ii) contain a combination of ingredients that produces no significant difference between the compounded drug and comparable commercially available products; (iii) are almost never prescribed properly under the governing regulations; and (iv) are "prescribed" and produced in large quantities without regard to medical necessity or the regulations governing the appropriate use of compounded drug products, as part of unlawful arrangements with the Prescribing Defendants.

84. In short, the Fraudulent Compounded Pain Creams produced by Direct Rx, and prescribed by the Prescribing Defendants and their associates working in collusion with Direct Rx, serve no purpose other than to exploit the Insured's No-Fault benefits so as to financially benefit the Defendants.

i. Direct Rx Specializes in Large Scale Drug Compounding Activity in Violation of New York State and Federal Law Governing Drug Manufacturers and Outsourcing Facilities

85. As stated above, compounded drug products are only appropriate in limited circumstances, should be formulated for an individual patient's needs upon receipt of a valid prescription for an identified individual or a notation on a prescription stating that a compounded product is necessary for the identified patient, and should not be prescribed and dispensed as a matter of routine therapy. Moreover, compounded drug products should never replace an FDA-approved and commercially available pharmaceutical product that can fulfill the same pharmacological need for the patient.

86. The Pharmacy Defendants, however, blatantly exploit the No-Fault insurance reimbursement system by entering into collusive relationships involving the marketing and soliciting of prescriptions for the same predetermined Fraudulent Compounded Pain Creams that are dispensed again and again to numerous Insureds involved in minor fender-bender type accidents, generating millions of dollars in fraudulent billing to New York automobile insurers.

87. Direct Rx, acting under the guise of a neighborhood pharmacy, intentionally assembles set combinations of expensive drug ingredients solely to produce exorbitantly priced Fraudulent Compounded Pain Creams that they can use to generate huge volumes of inflated billing, as part of collusive, steering relationships with the Prescribing Defendants.

88. As stated above, in furtherance of the scheme, the Pharmacy Defendants give the Prescribing Defendants preprinted labels or rubber stamps setting forth the predetermined, pre-formulated Fraudulent Compounded Pain Creams that Direct Rx creates, and/or a series of preprinted labels or rubber stamps, including the designated formulation, the names of the particular drug ingredients and the percentage concentrations of each ingredient used.

89. For example, the Pharmacy Defendants produce, market and dispense, among others, the following predetermined, formulaic Fraudulent Compounded Pain Creams:

(i) "Compound RX 220N" containing the following ingredients:
- Ketoprofen
- Baclofen
- Lidocaine
- Gabapentin
- Cyclobenzaprine
- Ethoxy Diglycol
- Pentravan Cream

(ii) "Compound RX 220W" containing the following ingredients:
- Lidocaine
- Gabapentin
- Flurbiprofen
- Ethoxy Diglycol
- Baclofen
- Cyclobenzaprine
- Pentravan Cream

(iii)"Compound RX 3" containing the following ingredients:
- Flurbiprofen
- Baclofen
- Cyclobenzaprine
- Gabapentin
- Imipramine
- Ethoxy Diglycol
- Versapro Cream

(iv)"Compound RX 218N" containing the following ingredients:
- Lidocaine
- Ketoprofen
- Ibuprofen
- Baclofen

- Cyclobenzaprine
- Ethoxy Diglycol
- Gabapentin
- Pentravan Cream

(v) "Compound RX 4" containing the following ingredients:

- Flurbiprofen
- Baclofen
- Cyclobenzaprine
- Gabapentin
- Imipramine
- Ethoxy Diglycol
- Menthol
- Versapro Cream

90. The Pharmacy Defendants typically bill GEICO (i) $871.10 for a single tube of Compound RX 220 N, (ii) between $1177.77 to $1493.54 for a single tube of Compound RX 220W, (iii) $1099.83 for a single tube of Compound RX 3, (iv) between $923.10 and $1439.54 for a single tube of Compound RX 218N, and (v) between $1095.39 to $1130.52 for a single tube of Compound RX 4.

91. The combination of drugs used in the Fraudulent Compounded Pain Creams is merely a means for the Defendants to inflate the billing and maximize their charges to exploit New York automobile insurance carriers, as pharmacy providers are ordinarily statutorily reimbursed for each individual ingredient contained in a compounded drug product. As a result, the more drug ingredients that Direct Rx includes in its Fraudulent Compounded Pain Creams, the more that the Pharmacy Defendants can bill under the name of Direct Rx.

92. Further, despite the fact that, according to the FDA, traditional pharmacy compounding requires the combining, mixing or altering of ingredients to create a customized medication for an individual patient in response to a licensed practitioner's prescription, the prescriptions using preprinted labels and/or rubber stamps and Prescription Forms – created by the Pharmacy Defendants and distributed to the prescribing physicians, including the Prescribing

Defendants – indicate that the Pharmacy Defendants create predetermined compounded drug products that are produced in bulk.

93. The pre-formulated Fraudulent Compounded Pain Creams are not created or prescribed by the Prescribing Defendants to meet the unique needs of an individual patient.

94. The Fraudulent Compounded Pain Creams are produced and dispensed by Direct Rx in large quantities without regard to the unique needs of any individual patient.

95. In fact, Yakutilov, in his capacity as supervising pharmacist, created the pre-determined formulaic Fraudulent Compounded Pain Creams, including Compound RX 4, which the Pharmacy Defendants continue to create and dispense to this day.

96. Notably, the Pharmacy Defendants never cite a legitimate medical need for the Fraudulent Compounded Pain Creams that would explain why a commercially available drug product is not appropriate to dispense to the Insureds who receive the Fraudulent Compounded Pain Creams.

97. Likewise, the Prescribing Defendants never cite a legitimate medical need for the Fraudulent Compounded Pain Creams that would explain why a commercially available drug product is not appropriate to prescribe for the Insureds who receive the Fraudulent Compounded Pain Creams. For example, the Prescribing Defendants never indicate the patient has a contradiction to commercially available drug products, and rarely do they document any medication allergies or pre-existing comorbidities that may support the use of Fraudulent Compounded Pain Creams.

98. Accordingly, the Fraudulent Compounded Pain Creams, prescribed by the Prescribing Defendants, and produced by the Pharmacy Defendants, are never customized for individual patients.

99. The Fraudulent Compounded Pain Creams vary only in that there are a limited number of predetermined Fraudulent Compounded Pain Creams from which to choose.

100. Direct Rx, by specializing in creating and dispensing large volumes of the Fraudulent Compounded Pain Creams, engages in bulk compounding activity (akin to that engaged in by drug manufacturers and outsourcing facilities) as opposed to compounding individual prescriptions on a case-by-case basis upon receipt of a valid prescription order.

101. Direct Rx's bulk compounding activity requires it to register as a manufacturer or outsourcing facility with the New York State Department of Education, as well as with the FDA, rather than registering as a mere pharmacy.

102. Direct Rx directly violated, and continues to violate, Federal and New York State regulatory and licensing requirements that govern large-scale drug compounders, drug manufacturers and outsourcing facilities and which prohibit collusive agreements for compounding and/or dispensing of coded or specially marked prescriptions, which pose a significant threat to the health and safety of the patients.

103. Direct Rx, to-date, has billed GEICO alone in excess of $1.5 million for the Fraudulent Compounded Pain Creams it created, produced and dispensed pursuant to the duplicitous prescriptions solicited from the Prescribing Defendants.

104. GEICO makes up only a fraction of the New York automobile insurance market, meaning that in all likelihood Direct Rx billed all New York automobile insurers more than three times the amount billed to GEICO.

105. Accordingly, since its inception, Direct Rx has likely created and dispensed massive volumes of the Fraudulent Compounded Pain Creams to patients resulting in millions and millions of dollars in claims submitted to various insurers.

106. The Pharmacy Defendants' creation and dispensation of predetermined, compounded drug products in large volumes, renders Direct Rx in violation of both state and federal licensing laws regulating the safe manufacturing of drugs.

107. Direct Rx and the Fraudulent Compounded Pain Creams are not exempt from FDA oversight and approval, and from similar New York State licensing requirements applicable to drug manufacturers and outsourcing facilities, because the Fraudulent Compounded Pain Creams are illegally compounded in set formulations in large quantities, rather than individualized and tailored to meet specific individual patient needs and provided pursuant to legitimate prescriptions. See 21 U.S.C. § 355 and 21 U.S.C. 353a(a).

108. Furthermore, as drug manufacturers and dispensers, the Pharmacy Defendants violated 21 U.S.C. § 355(a) which states that "no person shall introduce or deliver for introduction into interstate commerce any new drug" without first obtaining approval to do so by way of an application filed with the Secretary with respect to that drug.

109. A "new drug" – as defined by 21 U.S.C. § 321(p)(1) – is "any drug…the composition of which is such that such drug is not generally recognized…as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling thereof."

110. Direct Rx's Fraudulent Compounded Pain Creams – for which it has billed GEICO in excess of a million dollars – have never been FDA-approved and, therefore, were never verified by the FDA as being safe, effective or quality products. In fact, Direct Rx's bulk compounding and dispensing of the Fraudulent Compounded Pain Creams exposes Insureds to widespread risks including harmful contraindications, which is why they should only be prescribed under unique circumstances in limited circumstances.

ii. The Prescription and Dispensation of Direct Rx's Compounded Pain Creams Is Contrary to Evidenced-Based Medical Practices

111. In keeping with the fact that the Fraudulent Compounded Pain Creams are prescribed pursuant to the Defendants' fraudulent scheme intended to generate profits from insurers, Direct Rx's Fraudulent Compounded Pain Creams (i) have no medical efficacy based on the purported symptoms of the patients receiving the compounded products and (ii) are prescribed without any legitimate reason to provide the patients with expensive compounded products – which include drugs whose efficacy in topical form is undocumented and unsupported – when there are many other widely accepted, proven effective alternatives with well-documented therapeutic benefits commercially available at considerably lower costs.

112. Evidence-based guidelines for the treatment of acute pain do exist and should always guide prescribing habits. The World Health Organization ("WHO") pain relief ladder recommends a non-opioid such as acetaminophen or a nonsteroidal anti-inflammatory drug ("NSAID") for the initial management of pain. NSAIDs are the most commonly prescribed analgesic medications worldwide, and their efficacy for treating acute pain has been well demonstrated. If pain relief is not achieved, and doses are maximized, then an adjuvant oral agent may be added to the medication regimen – including the use of muscle relaxers, and medications that block neuropathic pain transmission. Finally, opiates may be prescribed for short-term, limited use. Clinical studies of FDA-approved topical NSAIDs have shown them to be no more effective than placebo for treating acute pain (e.g., from strains, sprains, contusions, or overuse injuries) in superficial locations.

113. Because compounded products, like the ones dispended by Direct Rx, are not FDA-approved – and therefore not subject to FDA regulations regarding quality, safety and effectiveness of manufactured drug products – they should never be prescribed as routine

therapy. Rather, they should only be prescribed to meet a legitimate specific need of an individual patient, or when all other forms of oral and/or topical medications approved for the treatment of pain have failed, or there is a contraindication for use.

114. Prior to receiving a prescription for any compounded pain product, a patient's medical records should document all other forms of FDA-approved drugs that were prescribed and failed to treat the symptoms which the compounded drug product was then prescribed, and/or the medical rationale that supports the otherwise premature prescription of a compounded drug product.

115. Topical compounded pain creams should be the last prescribed intervention, after oral medications are not tolerated, are deemed ineffective, or contraindicated, as well as after any FDA-approved topical products have been shown to provide no pain relief to the patient.

116. In order for a topical formulation to be effective, it must first penetrate the skin. In general, creams are less effective than gels or sprays.

117. The skin is composed of three layers: epidermis, dermis, and hypodermis. Within the epidermis, the stratus corneum is the outermost layer of the skin that serves as the main barrier to drug entry. For analgesic medicines to be absorbed through the skin, they must contain optimal drug combinations, effective concentrations of each drug, and a compounding base with the appropriate physiochemical properties to facilitate absorption.

118. In order for a drug to alleviate pain, it must reach nerve or tissue receptors responsible for producing or transmitting a person's sensation of pain.

119. Oral pain relievers reduce or alleviate pain by entering the bloodstream through the gastrointestinal system and traveling to the relevant nerve or tissue receptors. Some of the limited circumstances in which a physician would prescribe a topical medication include patients

in whom these oral medications are contraindicated – those with moderate to severe kidney or liver dysfunction, or those with comorbidities that preclude the use of oral nonsteroidal anti-inflammatory drugs (e.g., history of peptic ulcer disease or congestive heart failure).

120. Direct Rx's Fraudulent Compounded Pain Creams contain combinations of drugs that make no clinical sense and have no efficacious value in treating musculoskeletal and neuropathic injuries – even assuming that the Insureds the Prescribing Defendants treat actually suffered from such injuries.

121. There are no published, peer-reviewed, controlled studies to support that patients who suffer from musculoskeletal pain or neuropathy have achieved any therapeutic effect from using topical pain creams containing the drugs that are part of the Fraudulent Compounded Pain Creams.

122. Further, many of the Fraudulent Compounded Pain Creams are available in alternative oral formulations, or are commercially available in different topical formulations.

123. The alternatives to the Fraudulent Compounded Pain Creams, whether in oral formulations or commercially available topical formulations, have proven to therapeutically benefit patients with musculoskeletal and neuropathic pain, are FDA-approved, and are commonly prescribed by healthcare providers who utilize evidence-based medicine for their prescribing practices.

124. Contrary to evidenced-based medical practices, the Fraudulent Compounded Pain Creams are routinely prescribed by the Prescribing Defendants and administered without regard to whether other forms of oral and/or topical medications approved for the treatment of pain have failed, or there is a contraindication for their use.

125. The Prescribing Defendants failed to practice evidence-based medicine; rather, the Prescribing Defendants prescribed the Fraudulent Compounded Pain Creams based on their illegal, collusive arrangements with the Pharmacy Defendants that employed a fraudulent predetermined treatment and billing protocol designed to financially enrich all of the Defendants.

126. Even if the Prescribing Defendants knew about, and authorized, the prescriptions for particular Fraudulent Compounded Pain Creams, the Prescribing Defendants failed to recommend that the Insureds first try over-the-counter or prescription FDA-approved topical medications and to assess their effectiveness, prior to prescribing the Fraudulent Compounded Pain Creams produced and dispensed by the Pharmacy Defendants in large quantities.

127. The Prescribing Defendants also do not document in their examination reports whether the patients are intolerant of commercially available products, or whether any commercially available products were recommended to the patient.

128. The Prescribing Defendants also do not document in their examination reports why any compounded drug product was medically necessary and any contraindication to oral NSAIDs, or why the particular Fraudulent Compounded Pain Cream they ultimately prescribed for the patient was medically necessary.

129. The Prescribing Defendants also continuously fail to document in their follow-up examination reports whether the Fraudulent Compounded Pain Cream prescribed to a particular patient was actually used by the patient.

130. The Prescribing Defendants also continuously fail to document in their follow-up examination reports whether the Fraudulent Compounded Pain Cream provided any pain relief to the patient or was otherwise effective for the purpose prescribed.

131. The Prescribing Defendants plainly and continuously fail to prescribe individually tailored compounded products, made for an identified individual Insured, which produce a significant difference between the compounded drug and a comparable commercially available product.

132. Likewise, Direct Rx never dispenses individually tailored compounded products, made for an identified individual Insured, which produce a significant difference between the compounded drug and a comparable commercially available product.

D. The Fraudulent Diclofenac Gel Prescriptions

133. As a further part of the fraudulent scheme, the Pharmacy Defendants routinely billed GEICO for exorbitantly priced topical pain gels, ointments and lotions, primarily in the form of Diclofenac Sodium 3% topical gel ("Diclofenac Gel"), pursuant to prescriptions purportedly authorized by various physicians operating from No-Fault Clinics, including the Prescribing Defendants.

134. The FDA requires that diclofenac sodium prescriptions contain a "Black Box Warning" indicating serious cardiovascular and gastrointestinal risks.

135. A "Black Box Warning" is the strictest warning attached to the labeling of a prescription drug or product by the FDA, and is designed to call attention to serious or life-threatening risks associated with the drug or product.

136. Specifically, every diclofenac sodium prescription is required by the FDA to warn the patient that: (i) diclofenac sodium may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal; and (ii) diclofenac sodium may cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal.

137. Nevertheless, the Prescribing Defendants and other prescribing physicians routinely prescribe diclofenac sodium in the form of Diclofenac Gel that is dispensed by Direct Rx, oftentimes while recommending the patient continue the use of NSAIDs, such as naproxen, or simultaneously prescribing NSAIDs and other Fraudulent Pain Products such as topical pain patches. This duplication of therapy increase the adverse side effects associated with these pharmaceutical products.

138. The prescribing physicians consciously prescribe Diclofenac Gel in conjunction with NSAIDs and/or topical pain patches to numerous Insureds, despite the risks it poses to Insureds' health and wellbeing. In fact, by prescribing NSAIDs such as naproxen in conjunction with Diclofenac Gel, the Prescribing Defendants are putting patients at increased risk of serious cardiovascular and gastrointestinal events as the use of NSAIDs increases these "Black Box Warning" risks associated with diclofenac sodium.

139. The Diclofenac Gel is prescribed pursuant to predetermined treatment protocols and without regard for patient care and safety, or the commercial availability of a wide range of FDA-approved medications, as well as over-the-counter medications, proven to have therapeutic effects and available at a fraction of the cost.

140. In keeping with the fact that the Diclofenac Gel dispensed by Direct Rx is being prescribed and dispensed pursuant to predetermined treatment protocols and without regard for patient care and safety, the initial examination reports prepared by the Prescribing Defendants virtually never state the medical basis for the prescriptions and, in some cases, fail to acknowledge that the patient is even being prescribed diclofenac sodium.

141. In further keeping with the fact that the Diclofenac Gel dispensed by Direct Rx is prescribed and dispensed pursuant to predetermined treatment protocols and without regard for

patient care, the follow-up examination reports performed by the Prescribing Defendants virtually never address whether the Diclofenac Gel provided any pain relief to the patient or was otherwise effective for the purpose prescribed, to what degree, or whether the patients experienced any side effects.

142. In addition to the egregious number of Diclofenac Gel prescribed and dispensed by the Defendants to Insureds, the Prescribing Defendants purport to prescribe, and the Pharmacy Defendants submit exorbitant claims for various other topical pain lotions and ointments including Lidocaine 5% ointment.

143. In keeping with the fact that the Defendants submit or cause to be submitted bills pursuant to a profit-driven, fraudulent treatment protocol, the Lidocaine ointments are often prescribed contemporaneous to over-the-counter oral NSAIDs. At times, Lidocaine ointments are even prescribed and dispensed contemporaneous to Diclofenac Gel.

144. As with the prescriptions for the Diclofenac Gel, the examination reports prepared by the Prescribing Defendants virtually never set forth the medical basis for the prescriptions for Lidocaine ointment.

145. The fact that the Prescribing Defendants failed to properly document –or at times even document at all – the prescriptions for Diclofenac Gel and Lidocaine ointments, or the Insureds' use of these medications, further indicates that there is no legitimate medical reason for the Prescribing Defendants to prescribe large volumes of these medications to Insureds, particularly given the potential for adverse health effects.

146. Not surprisingly, the OIG in its August 2018 report on questionable billing for topical compounded drugs, noted that one of the most common products billed for by pharmacies with questionable billing was diclofenac sodium because, among other reasons, there is a striking

difference between the cost of a compounded topical containing diclofenac sodium and an non-compounded version of the same drug.

E. The Fraudulent Pain Patch Prescriptions

147. As a further part of their scheme, the Prescribing Defendants prescribe and the Pharmacy Defendants purport to dispense various pain patches – primarily in the form of Terocin Patches but also including Lidoderm 5% Patches (the "Fraudulent Pain Patches").

148. In keeping with the fact that the Fraudulent Pain Products are prescribed pursuant to predetermined treatment and billing protocols designed to maximize profits without regard to patient care, the Defendants prescribe, dispense and bill for the Fraudulent Pain Patches at exorbitant prices despite the fact that there are other, less expensive, commercially available FDA approved patches available.

149. For example, the Pharmacy Defendants dispensed and billed for Terocin 4% Patches – a non-prescription item – at a charge of $1,410.30 per prescription.

150. Not only are Terocin Patches available for purchase at a fraction of that price, but in addition to menthol, the primary ingredient in Terocin Patches is Lidocaine which itself is available in an FDA approved patch for a fraction of the cost. In fact, the Pharmacy Defendants dispense and bill for Lidocaine Patches at a charge of $246.60 to $739.80 per prescription.

151. As with the Fraudulent Compounded Drugs, many patients are not aware they are to receive any Fraudulent Pain Patches until the patches are given to them by the receptionists at the No-Fault Clinics or are mailed to the patients' homes.

152. In keeping with the fact that the Defendants act with gross indifference to patient care and safety, the patients are generally not instructed on the safe use, side effects or risks associated with the Fraudulent Pain Patches which may include blood toxicity, eye irritation from inadvertent contact, and symptoms of overdose if not used correctly.

153. In further keeping with the fact that the Fraudulent Pain Patches are prescribed, dispensed and billed pursuant to the Defendants' fraudulent treatment protocol designed to maximize profit without regard to patient care, the Fraudulent Pain Patches are almost always prescribed simultaneous to other Fraudulent Pain Products such as Diclofenac Gel, as well as NSAIDs.

F. The Exploiting of Patients for Financial Gain Through the Illegal, Collusive Arrangements Between the Pharmacy Defendants and the Prescribing Defendants

154. New York's statutory framework provides, among other things, that physicians and physician's assistants are prohibited from (i) "exercising undue influence" on a patient by promoting the sale of drugs so as to exploit the patient for the financial gain of the licensee or of a third party, and (ii) "directly or indirectly" giving, soliciting, receiving, or agreeing to receive any fee or other consideration to or from a third party in connection with the performance of professional services.

155. New York's statutory framework also specifically prohibits collusive arrangements between licensed physicians and pharmacies involving compounded or specially marked prescriptions. See Education Law § 6530(38) and § 6811(7). In fact, New York Education Law § 6811(7) makes such agreements criminal.

156. Here, the Pharmacy Defendants arrange with the Prescribing Defendants and their associates at various No-Fault Clinics, which treat thousands of Insureds to have the Prescribing Defendants, prescribe, or purport to prescribe, the Fraudulent Pain Products, including the Fraudulent Compounded Pain Creams, the Diclofenac Gel, and the Fraudulent Pain Patches, which in turn permits the Pharmacy Defendants to bill GEICO for huge sums under the name of Direct Rx.

157. In furtherance of the scheme, the Prescribing Defendants intentionally prescribe, or purport to prescribe, the Fraudulent Pain Products to patients of the No-Fault Clinics pursuant to the Defendants' fraudulent predetermined protocols, without regard to genuine patient care, without regard to cost and attention to fiscal responsibility, and often without regard to pharmacologic outcomes.

158. The Prescribing Defendants prescribe, or purport to prescribe, many of the Fraudulent Pain Products to patients of the No-Fault Clinics using the formulaic, coded "prescriptions" that contain preprinted labels or rubber stamps with the name and formula of one of the Fraudulent Compounded Pain Creams produced and dispensed by Direct Rx.

159. The Prescribing Defendants prescribe, or purport to prescribe, the Fraudulent Pain Products to patients of the No-Fault Clinics, despite their knowledge that they are involved in illegal, collusive arrangements designed to exploit the patents for financial gain; that the Fraudulent Compounded Pain Creams are not customized or tailored to the individual needs of a particular patient; the Fraudulent Pain Products are often being prescribed without regard to pharmacologic outcomes; the Fraudulent Pain Products are often being prescribed with gross indifference to patient care and safety; and that the Fraudulent Pain Products are prescribed without attention to cost and fiscal responsibility given that there are FDA-approved drugs available and appropriate for the particular patients at significantly less cost.

160. The Pharmacy Defendants virtually never give the Insureds the option to use a pharmacy of their choosing, rather the Prescribing Defendants direct the prescriptions for the Fraudulent Pain Products to Direct Rx, notwithstanding that (i) in many instances the Prescribing Defendants and the patients are located in counties far from Direct Rx in Richmond Hill, NY and

(ii) there are countless other pharmacies located much closer to the Prescribing Defendants and the patients.

161. The Prescribing Defendants direct the prescriptions for the Fraudulent Pain Products to Direct Rx because the prescriptions were only being issued because of the illegal, collusive arrangements among the Pharmacy Defendants and the Prescribing Defendants. Any prescriptions that may be filled through other pharmacies are done so only to evade detection by GEICO of the fraudulent treatment protocol.

162. Direct Rx purports to mail or deliver the Fraudulent Pain Products directly to the Insureds' homes, in many cases, without the patient even knowing that they were to receive one or more of the Fraudulent Pain Products.

163. Alternatively, the Insureds sometimes are given the Fraudulent Pain Products directly from the front desk staff at the various No-Fault Clinics, in many cases, without even knowing that they were to receive one or more of the Fraudulent Pain Products.

164. In order to ensure that the prescriptions are filled by Direct Rx and to ensure that the Pharmacy Defendants benefit financially from the prescriptions, the Prescribing Defendants do not give the Insureds the option to identify a pharmacy of their choosing.

165. The Prescribing Defendants have no legitimate medical reason to prescribe the predetermined, medically unnecessary Fraudulent Pain Products in large quantities to their patients.

166. The Prescribing Defendants would not engage in the illegal, collusive arrangements with the Pharmacy Defendants in violation of New York law, including using preprinted labels and rubber stamps distributed by the Pharmacy Defendants, intentionally

prescribing medically unnecessary Fraudulent Pain Products, and directing those prescriptions to Direct Rx, unless they profited from their participation in the illegal scheme.

167. But for the payments of kickbacks, or other financial incentives from the Pharmacy Defendants, the Prescribing Defendants would not prescribe the Fraudulent Compounded Pain Creams, the Diclofenac Gel or the Fraudulent Pain Patches, or the volume of the other Fraudulent Pain Products, and would not direct the prescriptions to Direct Rx.

168. The Pharmacy Defendants and the Prescribing Defendants have affirmatively concealed the particular amounts paid for the kickbacks since such kickbacks are in violation of New York law.

169. Nevertheless, based on the circumstances surrounding the illegal, collusive, arrangements, the Pharmacy Defendants paid, and continue to pay, a financial kickback or provide other financial incentives, and the Prescribing Defendants received, and continue to receive, a financial kickback or other financial incentives, for each of the particular prescriptions for the Fraudulent Pain Products that are dispensed by Direct Rx. The payment of such kickbacks is made at or near the time the prescriptions are issued.

170. In keeping with the fact that the Prescribing Defendants prescribe, and the Pharmacy Defendants dispense the Fraudulent Pain Products in order to exploit the Insureds for financial gain without regard to patient care, patients are often prescribed medically unnecessary pharmaceutical products, often without appropriate documentation or referencing of such pharmaceutical products in the medical reports. For example,

- Patient [redacted] was allegedly involved in a motor vehicle accident on October 31, 2017. She did not seek hospital treatment. On November 8, 2017, she appeared at a No-Fault Clinic located at 1655 Richmond Avenue, Staten Island, NY where Prescribing Defendant Dr. Apple performed an initial examination and issued a prescription for a Fraudulent Compounded Pain Cream, specifically Compound RX 4. Notably, Dr. Apple makes no reference as to the

prescribed Compound RX 4 in the "Recommendations" section of his initial examination report. Moreover, Dr. Apple indicated in the "Medications" section of his initial examination report that patient N.Z. was taking Ibuprofen as a medication but then fails to state the basis for prescribing the Fraudulent Compounded Pain Cream. On November 13, 2017, Direct Rx filled the prescription for the Fraudulent Compounded Pain Cream. Dr. Apple performed follow-up examinations on December 27, 2017, January 31, 2018, and March 14, 2018. The follow-up examination reports do not make any reference as to whether the patient was using the Fraudulent Compounded Pain Cream or receiving any benefit and/or experiencing side effects from it. The Pharmacy Defendants billed GEICO at least $1,095.39 for pharmaceutical products allegedly prescribed and dispensed to this patient.

- Patient [redacted] was allegedly involved in a motor vehicle accident on October 30, 2017. He was reportedly transported via ambulance to a hospital and then refused medical treatment. On November 15, 2017, he appeared at a No-Fault Clinic located at 1655 Richmond Avenue, Staten Island, NY where Prescribing Defendant Dr. Apple performed an initial examination and issued a prescription for a Fraudulent Compounded Pain Cream, specifically Compound RX 4. Notably, Dr. Apple indicated in the "Medications" section of this initial examination report that patient V.S. was taking Ibuprofen as a medication but then fails to state the basis for prescribing the Fraudulent Compounded Pain Cream. On November 18, 2019, Direct Rx filled the prescription for the Fraudulent Compounded Pain Cream. Dr. Apple performed follow-up examinations on January 17, 2018, March 28, 2018, and April 25, 2018. The follow-up examination reports do not make any reference as to whether the patient was using the Fraudulent Compounded Pain Cream or receiving any benefit and/or experiencing side effects from it. The Pharmacy Defendants billed GEICO at least $1,095.39 for pharmaceutical products allegedly prescribed and dispensed to this patient.

- Patient [redacted] was allegedly involved in a motor vehicle accident on November 9, 2017. She reportedly was treated at the scene of the accident by EMS but did not seek hospital medical treatment. On November 15, 2017, she appeared at a No-Fault Clinic located at 1655 Richmond Avenue, Staten Island, NY where Prescribing Defendant Dr. Apple performed an initial examination and issued a prescription for a Fraudulent Compounded Pain Cream, specifically Compound RX 4. Notably, Dr. Apple indicated in the "Medications" section of this initial examination report that patient N.S. was taking Ibuprofen as a medication but then fails to state the basis for prescribing the Fraudulent Compounded Pain Cream. On November 18, 2017, Direct Rx filled the prescription for the Fraudulent Compounded Pain Cream. Dr. Apple performed a follow-up examination on December 20, 2017, January 24, 2018, April 4, 2018, and May 16, 2018. The follow-up examination reports do not make any reference as to whether the patient was using the Fraudulent Compounded Pain Cream or receiving any benefit and/or experiencing side effects from it. The Pharmacy

Defendants billed GEICO at least $1095.39 for pharmaceutical products allegedly prescribed and dispensed to this patient.

- Patient [redacted] was allegedly involved in a motor vehicle accident on October 31, 2017. He did not report any injuries at the scene of the accident and refused medical treatment. On November 8, 2017, he appeared at a No-Fault Clinic located at 1655 Richmond Avenue, Staten Island, NY where Prescribing Defendant Dr. Apple performed an initial examination and issued a prescription for a Fraudulent Compounded Pain Cream, specifically Compound RX 4. Notably, Dr. Apple fails to state the basis for prescribing the Fraudulent Compounded Pain Cream instead of NSAIDs in the initial examination report. Direct Rx filled the prescription for the Fraudulent Compounded Pain Cream on November 13, 2017. Dr. Apple performed a follow-up examination on December 13, 2017. The follow-up examination report does not make any reference as to whether the patient was using the Fraudulent Compounded Pain Cream or receiving any benefit and/or experiencing side effects from it. Dr. Apple performed another follow-up examination on February 7, 2018 where Dr. Apple issued a prescription for Fraudulent Pain Patches, specifically, Lidocaine 5% Patches. The February 7, 2018 follow-up examination report also failed to make any reference as to the previously prescribed Compound RX 4. Moreover, the follow-up examination report also failed to state the basis for prescribing the Fraudulent Pain Patches. The Pharmacy Defendants billed GEICO at least $1,835.19 for pharmaceutical products allegedly prescribed and dispensed to this patient.

To date, Prescribing Defendant Dr. Apple caused at least $215,086.41 in fraudulent billing to be submitted to GEICO through the Pharmacy Defendants.

- Patient [redacted] was allegedly involved in a motor vehicle accident on June 8, 2017. She refused medical treatment by Emergency Medical Services ("EMS") at the scene of the accident. She went to an immediate care center several hours later on the same day where she underwent an examination and X-Rays were taken. She was issued a seven-day prescription for Naprosyn 500 mg and Cyclobenzaprine 10 mg. On June 12, 2017, she appeared at a No-Fault Clinic located at 90-04 Merrick Blvd, Jamaica, NY where Prescribing Defendant Dr. Delacruz-Gomez performed an initial examination and issued a prescription for a Fraudulent Compounded Pain Cream, specifically Compound RX 4 with one refill. Notably, there is no mention of the prescriptions for Naprosyn and Cyclobenzaprine previously issued to the patient in the "Medication" section of Dr. Delacruz-Gomez's initial examination report. Direct Rx filled the prescription for the Fraudulent Compounded Pain Cream on June 19, 2017 and the refill for the same on July 12, 2017. Dr. Delacruz-Gomez performed follow-up examinations on August 1, 2017 and September 5, 2017. The follow-up examination reports do not make any reference as to whether the patient was using the Fraudulent Compounded Pain Cream or receiving any benefit and/or

experiencing side effects from it. Further, none of the examination reports indicate the basis for prescribing Fraudulent Compounded Pain Creams instead of NSAIDs. The Pharmacy Defendants billed GEICO at least $2,944.78 for pharmaceutical products allegedly prescribed and dispensed to this patient.

- Patient [redacted] was allegedly involved in a motor vehicle accident on September 15, 2017. She did not report any injuries at the scene of the accident. On September 20, 2017, she appeared at a No-Fault Clinic located at 90-04 Merrick Blvd., Jamaica, NY where Prescribing Defendant Dr. Delacruz-Gomez performed an initial examination and issued a prescription for a Fraudulent Compounded Pain Cream, specifically Compound RX 4 with one refill. Direct Rx filled the prescription for the Fraudulent Compounded Pain Cream on October 2, 2017 and the refill for the same on November 11, 2017. Dr. Delacruz-Gomez performed follow-up examinations on October 17, 2017, November 13, 2017 and January 10, 2018. The follow-up examination reports do not make any reference as to whether the patient was using the Fraudulent Compounded Pain Cream or receiving any benefit and/or experiencing side effects from it. Further, none of the examination reports indicate the basis for prescribing the Fraudulent Compounded Pain Creams instead of NSAIDs. Direct Rx filled the prescription for the Fraudulent Compounded Pain Creams on October 2, 2017 and November 11, 2017. The Pharmacy Defendants billed GEICO at least $2,360.16 for pharmaceutical products allegedly prescribed and dispensed to this patient.

- Patient [redacted] was allegedly involved in a motor vehicle accident (the same accident as D.W. referenced above). She did not report any injuries at the scene of the accident. On September 20, 2017, she appeared at a No-Fault Clinic located at 90-04 Merrick Blvd., Jamaica, NY where Prescribing Defendant Dr. Delacruz-Gomez performed an initial examination and as he did for patient D.W. issued her a prescription for a Fraudulent Compounded Pain Cream, specifically Compound RX 4 with one refill. Direct Rx filled the prescription for the Fraudulent Compounded Pain Cream on October 2, 2017 and the refill for the same on November 2, 2017. Dr. Delacruz-Gomez performed follow-up examinations on October 19, 2017, November 30, 2017, January 3, 2018, February 20, 2018 and March 19, 2018. The follow-up examination reports do not make any reference as to whether the patient was using the Fraudulent Compounded Pain Cream or receiving any benefit and/or experiencing side effects from it. Further, none of the examination reports indicate the basis for prescribing Fraudulent Compounded Pain Creams in lieu of NSAIDs. The Pharmacy Defendants billed GEICO at least $2,360.54 for pharmaceutical products allegedly prescribed and dispensed to this patient.

- Patient [redacted] was allegedly involved in a motor vehicle accident (the same accident as D.W. and K.A. referenced above). She did not report any injuries at the scene of the accident. On September 21, 2017, she appeared at a No-Fault Clinic located at 90-04 Merrick Blvd., Jamaica, NY where Prescribing Defendant Dr. Delacruz-Gomez performed an initial examination and as he did

for patient D.W. and K.A., issued her a prescription for a Fraudulent Compounded Pain Cream, specifically Compound RX 4 with one refill. Direct Rx filled the prescription for the Fraudulent Compounded Pain Cream on October 2, 2017 and the refill for the same on November 2, 2017. Dr. Delacruz-Gomez performed follow-up examinations on November 1, 2017, December 4, 2017, January 22, 2018, February 21, 2018 and April 3, 2018. The follow-up examination reports do not make any reference as to whether the patient was using the Fraudulent Compounded Pain Cream or receiving any benefit and/or experiencing side effects from it. Further, none of the examination reports indicate the basis for prescribing Fraudulent Compounded Pain Creams in instead of NSAIDs. The Pharmacy Defendants billed GEICO at least $2,365.54 for pharmaceutical products allegedly prescribed and dispensed to this patient.

To date, Prescribing Defendant Dr. Delacruz-Gomez caused at least $947,356.39 in fraudulent billing to be submitted to GEICO through the Pharmacy Defendants.

- Patient [redacted] was allegedly involved in a motor vehicle accident on November 4, 2015. He did not report any injuries at the scene of the accident but appeared at a hospital later on the same day. He was administered Ibuprofen while in the Emergency Department and discharged. On January 12, 2016, approximately two months after the alleged motor vehicle accident, he appeared at a No-Fault Clinic located at 1655 Richmond Ave, Staten Island, NY where Prescribing Defendant Dr. Barakat performed an initial examination. Dr. Barakat performed follow-up examinations on February 16, 2016, March 22, 2016, April 29, 2016, May 27, 2016 and July 5, 2016. During the February 16, 2016 follow-up examination, Dr. Barakat prescribed a Fraudulent Compounded Pain Cream. On March 25, 2016, Dr. Barakat prescribed Terocin Patches. Notably, Dr. Barakat did not issue the prescription for the Terocin Patches on the day that the patient was examined. Instead, Dr. Barakat issued the prescription three days after the follow-up examination. The follow-up examination reports do not make any reference as to whether the patient was using the Fraudulent Compounded Pain Cream and the Terocin Patches or receiving any benefit and/or experiencing side effects from either prescription. Further, none of the examination reports indicate the basis for prescribing Fraudulent Compounded Pain Creams and Terocin Patches instead of NSAIDs. The Pharmacy Defendants billed GEICO at least $1,410.30 for pharmaceutical products allegedly prescribed and dispensed to this patient.

- Patient [redacted] was allegedly involved in a motor vehicle accident on February 19, 2015. He did not report any injuries at the scene of the accident and did not seek medical treatment. On March 12, 2015, he appeared at a No-Fault Clinic located at 1655 Richmond Ave, Staten Island, NY where Prescribing Defendant Dr. Barakat performed an initial examination and issued a prescription for a Fraudulent Compounded Pain Cream. Notably,

under the "Medication" section of his initial examination report, Dr. Barakat indicates that the patient was taking NSAIDs, specifically, Ibuprofen and a muscle relaxant but then fails to mention the prescription for Fraudulent Compounded Pain Creams. Dr. Barakat performed follow-up examinations on April 10, 2015, August 21, 2015 and September 29, 2015. The follow-up examination reports do not make any reference as to whether the patient was using the Fraudulent Compounded Pain Cream or receiving any benefit and/or experiencing side effects from it. Further, none of the examination reports indicate the basis for prescribing Fraudulent Compounded Pain Creams in addition to the NSAIDs the patient was already taking. The Pharmacy Defendants billed GEICO at least $937.74 for pharmaceutical products allegedly prescribed and dispensed to this patient.

- Patient [redacted] was allegedly involved in a motor vehicle accident on February 10, 2015. He did not report any injures at the scene of the accident. However, hours later the patient appeared at a hospital. The patient was administered Ibuprofen in the Emergency Department and issued a prescription for Tizandine (20 tablets with no re-fill), a muscle relaxant and discharged. On February 12, 2015, he appeared at a No-Fault Clinic located at 1655 Richmond Ave, Staten Island, NY where Prescribing Defendant Dr. Barakat performed an initial examination. Dr. Barakat performed follow-up examinations on March 31, 2015, May 5, 2015 and July 2, 2015. On March 20, 2015, Dr. Barakat issued a prescription for a Fraudulent Compounded Pain Cream for the patient. Notably, Dr. Barakat issued this prescription eleven (11) days prior to performing the March 31, 2015 follow-up examination. Dr. Barakat issued another prescription for a Fraudulent Compounded Pain Cream during the July 2, 2015 follow-up examination. The follow-up examination reports do not make any reference as to whether the patient was using the Fraudulent Compounded Pain Cream or receiving any benefit and/or experiencing side effects from it. Further, none of the examination reports indicate the basis for prescribing Fraudulent Compounded Pain Creams instead of NSAIDs. The Pharmacy Defendants billed GEICO at least $1,925.64 for pharmaceutical products allegedly prescribed and dispensed to this patient.

- Patient [redacted] was allegedly involved in a motor vehicle accident on November 16, 2016. On November 22, 2016, he appeared at a No-Fault Clinic located at 1655 Richmond Ave, Staten Island, NY where Prescribing Defendant Dr. Barakat performed an initial examination and issued a prescription for a Fraudulent Compounded Pain Cream. Dr. Barakat performed follow-up examinations on December 22, 2016 and January 24, 2017 and issued prescriptions for Fraudulent Compounded Pain Cream on each date. Dr. Barakat also performed additional follow-up examinations on March 3, 2017 and April 26, 2017. The follow-up examination reports do not make any reference as to whether the patient was using the Fraudulent Compounded Pain Cream or receiving any benefit and/or experiencing side

effects from it. Further, none of the examination reports indicate the basis for prescribing Fraudulent Compounded Pain Creams instead of NSAIDs. The Pharmacy Defendants billed GEICO at least $4,085.19 for pharmaceutical products allegedly prescribed and dispensed to this patient.

To date, Prescribing Defendant Dr. Barakat caused at least $495,049.52 in fraudulent billing to be submitted to GEICO through the Pharmacy Defendants.

171. In keeping with the Defendants' profit driven fraudulent scheme and in an attempt to evade detection of said scheme, beginning in 2018, rather than primarily prescribing and dispensing Fraudulent Compounded Pain Creams, the Prescribing Defendants started prescribing and the Pharmacy Defendants dispensing voluminous amounts of medically unnecessary Diclofenac Gel to Insureds. For example:

- Patient [redacted] was allegedly involved in a motor vehicle accident on May 21, 2018. She did not report any injuries at the scene of the accident. On May 22, 2018, she appeared at a No-Fault Clinic located at 1655 Richmond Ave, Staten Island, NY where Prescribing Defendant Dr. Apple performed an initial examination and issued a prescription for Diclofenac Gel. Notably, Dr. Apple indicated in the "Medications" section of his initial examination report that patient S. Nesya was taking Ibuprofen. Yet, Dr. Apple still prescribed Diclofenac Gel by stamping "Diclofenac Sodium Gel 3%" under "Treatment Plan" section in the examination report and then failed to indicate the basis for the prescription or the discontinuation of Ibuprofen, which would be duplication of therapy and an increased risk of adverse events for this drug class.

- Patient [redacted] was allegedly involved in a motor vehicle accident on May 12, 2018. She did not report any injuries at the scene of the accident. On May 16, 2018, she appeared at a No-Fault Clinic located at 1655 Richmond Ave, Staten Island, NY where Prescribing Defendant Dr. Apple performed an initial examination and issued a prescription for Diclofenac Gel. Notably, Dr. Apple indicated in the "Medications" section of his initial examination report that patient C.F-Sciacca was taking Percocet, Tramadol, Robaxin, Morphine, as well as other medications. Yet, Dr. Apple still prescribed Diclofenac Gel by stamping "Diclofenac Sodium Gel 3%" under "Treatment Plan" section of the examination report and then failed to indicate the basis for the prescription.

- Patient [redacted] was allegedly in a motor vehicle accident on May 2, 2018. He did not report any injuries at the scene of the accident. On May 9, 2018, he

appeared at a No-Fault Clinic located at 1655 Richmond Ave, Staten Island, NY where Prescribing Defendant Dr. Apple performed an initial examination and issued a prescription for Diclofenac Gel. Notably, Dr. Apple indicated in the "Medications" section of his initial examination report that patient A.D. was taking Ibuprofen and Naproxen, as well as other medications. Yet, Dr. Apple still prescribed Diclofenac Gel by stamping "Diclofenac Sodium Gel 3%" under "Treatment Plan" section of the examination report and then failed to indicate the basis for the prescription. Dr. Apple performed a follow-up examination on June 6, 2018 and once again issued a prescription for Diclofenac Gel. The follow-up examination report does not make any reference as to whether the patient was using the Diclofenac Gel or receiving any benefit and/or experiencing side effects from it.

- Patient [redacted] was allegedly involved in a motor vehicle accident on December 15, 2018. On December 20, 2018, she appeared at a No-Fault Clinic located at 222-01 Hempstead Avenue, Queens Village, NY where Prescribing Defendant Dr. Delacruz-Gomez performed an initial examination and issued a prescription for Diclofenac Gel with one refill. Notably, Dr. Delacruz circles "compound" under the "Treatment Plan" section of the initial examination report but fails to reference which compound is being prescribed. Dr. Delacruz-Gomez performed follow-up examinations on January 17, 2019 and February 22, 2019. The follow-up examination reports do not make any reference as to whether the patient was using the Diclofenac Gel or receiving any benefit and/or experiencing side effects from it.

- Patient [redacted] was allegedly involved in a motor vehicle accident on May 5, 2018. He did not report any injuries at the scene of the accident and refused medical treatment by EMS. On May 9, 2018, he appeared at a No-Fault Clinic located at 222-01 Hempstead Avenue, Queens Village, NY where Prescribing Defendant Dr. Delecruz-Gomez performed an initial examination and issued a prescription for Diclofenac Gel with one refill. Notably, Dr. Delacruz circles "compound" under the "Treatment Plan" section of the initial examination report but fails to reference which compound is being prescribed.

- Patient [redacted] was allegedly involved in a motor vehicle accident (the same accident as E. Colon referenced above). She did not report any injuries at the scene of the accident and refused medical treatment by EMS. On May 9, 2018, she appeared at a No-Fault Clinic located at 222-01 Hempstead Avenue, Queens Village, NY where Prescribing Defendant Dr. Delecruz-Gomez performed an initial examination and as he did for patient E.Colon, issued a prescription for Diclofenac Gel with one refill. Notably, Dr. Delacruz circles "compound" under the "Treatment Plan" section of the initial examination report but fails to reference which compound is being prescribed.

- Patient [redacted] was allegedly involved in a motor vehicle accident on October 10, 2018. He did not report any injuries at the scene of the accident

and refused medical treatment by EMS. On October 16, 2018, he appeared at a No-Fault Clinic located at 4014-A Boston Rd., Bronx, NY where Prescribing Defendant Dr. Barakat issued a prescription for Lidocaine 5% Ointment. In his examination report, Dr. Barakat fails to indicate the basis for prescribing the Lidocaine 5% Ointment instead of NSAIDs.

- Patient [redacted] was allegedly involved in a motor vehicle accident on July 27, 2018. She did not report any injuries at the scene of the accident. On August 22, 2018, she appeared at a No-Fault Clinic located at 4014A Boston Rd., Bronx, NY where Prescribing Defendant Dr. Barakat performed an initial examination and issued a prescription for Lidocaine 5% Ointment. On September 26, 2018, Dr. Barakat performed a follow-up examination and issued a prescription for Lidocaine 5% Ointment. On October 24, 2018, Dr. Barakat performed a follow-up examination and issued a prescription for Lidocaine 5% Ointment and Tramadol (a narcotic). In his examination reports, Dr. Barakat fails to indicate the basis for prescribing Lidocaine 5% Ointment in conjunction with Tramadol.

- Patient [redacted] was allegedly involved in a motor vehicle accident on July 7, 2018. She appeared at a hospital and was administered Motrin and Flexeril. Patient S. Nino was discharged and issued a prescription for Cyclobenzaprine and Naproxen. On July 25, 2018, she appeared at a No-Fault Clinic located at 4014-A Boston Rd., Bronx, NY where Prescribing Defendant Dr. Barakat issued a prescription for Lidocaine 5% Ointment. On September 4, 2018 and October 9, 2018, Dr. Barakat performed a follow-up examination and issued a prescription for Lidocaine 5% Ointment on each date. Dr. Barakat fails to indicate the basis for prescribing the Lidocaine 5% Ointment instead of NSAIDs.

172. Notably, the Fraudulent Pain Products prescribed by the Prescribing Defendants account for at least 65% of the Fraudulent Pain Products dispensed by the Pharmacy Defendants.

V. The Fraudulent Billing the Defendants Submit or Cause to be Submitted to GEICO

173. Every prescription product, whether a brand name or generic drug, has a designated national drug code ("NDC") – a unique 10-digit code that identifies the drug itself, the vendor of the drug and the quantity in which the drug was packaged. Each NDC number has an assigned Average Wholesale Price ("AWP").

174. Each NDC (and, thus, the AWP) for a particular prescription product differs depending on both the particular supplier the drug is purchased from and the quantity in which

the drug is obtained. The same drug can have a different NDC number if it is purchased from a different supplier and/or in different quantities.

175. The maximum amount that a healthcare provider may charge for a medically necessary prescription drug or product is based upon the drug's NDC number. With respect to compounded products, the maximum that a healthcare provider may charge is based on each individual ingredient included in the compounded product and their corresponding NDC numbers and AWPs.

176. Pursuant to 12 N.Y.C.R.R. §§ 440.5(a) and (d) (the "Pharmacy Fee schedule"), for each brand name drug (or ingredient included in a compounded product) a provider may charge no more than the AWP assigned to that particular NDC on the day the drug was dispensed minus 12% of the AWP, plus a single dispensing fee of $4.00.

177. For each generic drug (or ingredient included in a compounded product) the provider may charge no more than the AWP assigned to that particular NDC on the day the drug was dispensed minus 20% of the AWP, plus a single dispensing fee of $5.00.

178. AWP is defined by 12 N.Y.C.R.R. § 440.2(a) as:

> "[t]he average wholesale price of a prescription drug as provided in the most current release of the Red Book published by Thomson Reuters or Medi-Span Master Drug Database by Wolters Kluwer Health or any successor publisher, on the day a prescription drug is dispensed or other nationally recognized drug pricing index adopted by the Chair or Chair's designee."

179. When a pharmacist bills for dispensing prescription drugs (including compounded products), it must bill based on the actual NDC number (and the assigned AWP) for that drug or compound drug ingredient. It cannot use the NDC of the same ingredient available from a different supplier and/or purchased in different quantities in order to inflate the assigned AWP.

180. The Pharmacy Defendants purport to provide the Fraudulent Pain Products, including the Fraudulent Compounded Pain Creams, directly to GEICO Insureds, and seek reimbursement directly from GEICO pursuant to executed "Assignment of Benefit" ("AOB") forms.

181. In support of its charges, the Pharmacy typically Defendants submit: (i) the Prescribing Defendants' prescription forms (ii) a "No-Fault" form, known as an NF-3 Form, which includes the purported NDC numbers, units, and corresponding charges for each drug product or ingredient; (iii) a delivery receipt from the Pharmacy Defendants; and (iv) the AOB in which the Insured assigns his benefits to the Pharmacy Defendants.

182. The NDC numbers listed on the NF-3 Forms submitted by the Pharmacy Defendants identify the AWPs for each of the prescriptions drugs or compound drug ingredients contained within the Fraudulent Compounded Pain Creams.

183. The Pharmacy Defendants never submit their bills purchase invoices demonstrating the actual product was purchased, how much the Pharmacy Defendants paid the supplier for the particular ingredients or the quantities in which ingredients were obtained.

184. The Defendants prescribe and dispense excessive amounts of pharmaceutical products to each Insured in order to inflate the charges and maximize their billing to exploit New York automobile insurance carriers, as pharmacy providers are ordinarily statutorily reimbursed for each individual drug, including each individual ingredient contained in a compounded drug product.

185. In keeping with the fact that the Pharmacy Defendants are engaged in a profit-driven scheme designed to inflate charges and maximize their billing to exploit New York automobile insurance carriers, despite the fact that the Pharmacy Fee Schedule requires a 12%

reduction of the AWP for brand name drug and a 20% reduction for generic drugs, the Pharmacy Defendants never apply these restrictions.

VI. The Defendants' Submission of Fraudulent NF-3 Forms to GEICO

186. To support the fraudulent charges, statutorily prescribed claim forms for No-Fault Benefits have been submitted to GEICO by and on behalf of Direct Rx seeking payment for the pharmaceuticals for which it is ineligible to receive payment.

187. These forms, including NF-3 forms, HCFA-1500 forms and other supporting records that the Defendants submitted or caused to be submitted to GEICO, were false and misleading in the following material respects:

(i) NF-3 forms, HCFA-1500 forms, and other supporting records uniformly misrepresent to GEICO that the Fraudulent Pain Products are medically necessary and intended for patient care. In fact, the Fraudulent Pain Products are the product of predetermined fraudulent protocols designed to exploit the patients for financial gain without regard for genuine patient care;

(ii) The NF-3 forms, HCFA-1500 forms, and other supporting records uniformly misrepresent to GEICO that the Pharmacy Defendants are in compliance with all material licensing requirements and, therefore, are eligible to receive No-Fault Benefits pursuant to Insurance Law § 5102(a)(1) and 11 N.Y.C.R.R. § 65-3.16(a)(12). In fact, the Pharmacy Defendants do not comply with all material licensing requirements in that the Defendants engage in illegal, collusive relationships with the Prescribing Defendants, including receiving illegal prescriptions from the Prescribing Defendants for the Fraudulent Pain Products in exchange for unlawful kickbacks and other financial incentives;

(iii) The NF-forms, HCFA-1500 forms, and other supporting records, uniformly misrepresent to GEICO that Pharmacy Defendants are in compliance with all material licensing laws and, therefore, are eligible to receive No-Fault Benefits pursuant to Insurance Law § 5102(a)(1) and 11 N.Y.C.R.R. § 65-3.16(a)(12). In fact, the Pharmacy Defendants do not comply with all material licensing laws in that they dispense the Fraudulent Pain Products pursuant to illegal, invalid, duplicitous and formulaic prescriptions; and

(iv) The NF-forms, HCFA-1500 forms, and other supporting records, uniformly misrepresent to GEICO that Pharmacy Defendants are in compliance with all material licensing requirements and, therefore, are eligible to receive No-Fault Benefits pursuant to Insurance Law § 5102(a)(1) and 11 N.Y.C.R.R. § 65-3.16(a)(12). In fact, the Pharmacy Defendants do not comply with all material licensing requirements in that they engage in illegal bulk compounding by producing and dispensing large quantities of the Fraudulent Compounded Pain Creams in set formulations, in violation of Federal and New York State regulatory and licensing requirements imposed on drug manufacturers and outsourcing facilities, rendering Direct Rx ineligible to receive reimbursement for No-Fault Benefits.

VII. The Defendants' Fraudulent Concealment and GEICO's Justifiable Reliance

188. The Defendants are legally and ethically obligated to act honestly and with integrity in connection with the provision of pharmaceutical products to Insureds and the billing they submit or cause to be submitted to GEICO seeking reimbursement for these products.

189. To induce GEICO to promptly pay the charges for the Fraudulent Compounded Drugs, the Defendants have gone to great lengths to systematically conceal their fraud.

190. Specifically, the Defendants knowingly have misrepresented and concealed facts in an effort to prevent discovery that the Defendants: (i) prescribe and dispense Fraudulent Pain Products pursuant to predetermined fraudulent protocols designed to exploit the patients for financial gain, without regard for genuine patient care; (ii) have been involved in illegal, collusive, agreements to generate the voluminous prescriptions pursuant to a fraudulent predetermined protocol; (iii) intentionally assembled large combinations of drugs into purported compounded pain creams solely to inflate the billing to GEICO and other New York insurance companies; and (iv) violate licensing laws governing manufacturers and large-scale drug outsourcing facilities of compounded drugs.

191. The Defendants also billed for the Fraudulent Pain Products based on purported prescriptions from multiple prescribing physicians and physician assistants in order to reduce the amount of billing based on any single licensee, and further billed for a multiple of pharmaceutical drug products, including various oral medications, in order to conceal the scheme to exploit the Insureds for financial gain.

192. The billing and supporting documentation submitted by the Defendants for the Fraudulent Pain Products, when viewed in isolation, does not reveal its fraudulent nature.

193. The Pharmacy Defendants have hired law firms to pursue collection of the fraudulent charges from GEICO and other insurers. These law firms routinely file expensive and time-consuming litigation against GEICO and other insurers if the charges are not promptly paid in full. In fact, the Direct Rx continues to have legal counsel pursue collection against GEICO and other insurers without regard for the fact that Direct Rx has been engaged in fraud.

194. GEICO is under statutory and contractual obligations to promptly and fairly process claims within 30 days. The facially-valid documents that were submitted to GEICO in support of the fraudulent charges at issue, combined with the material misrepresentations described above, were designed to and did cause GEICO to rely upon them. As a result, GEICO has incurred damages of approximately $548,369.00 representing payments made by GEICO based upon the fraudulent charges submitted by the Defendants, which damages are to be trebled under 18 U.S.C. § 1962(c)), et. al to$1,645,107.00.

195. Based upon the Defendants' material misrepresentations and other affirmative acts to conceal fraud from GEICO, GEICO did not discover and could not reasonably have discovered that its damages were attributable to fraud until shortly before it filed this Complaint.

THE FIRST CLAIM FOR RELIEF
Against the Pharmacy Defendants
(Declaratory Judgment – 28 U.S.C. §§ 2201 and 2202)

196. GEICO incorporates, as though fully set forth herein, each and every allegation in the paragraphs set forth above.

197. There is an actual case in controversy between GEICO and the Pharmacy Defendants regarding approximately $1,590,338.00 in fraudulent billing for the Fraudulent Pain Products that the Pharmacy Defendants submitted or caused to be submitted to GEICO through Direct Rx.

198. Direct Rx has no right to receive payment for any pending bills submitted to GEICO because:

(i) the billed-for services were not medically necessary and/or were the product of pre-determined fraudulent protocols designed to exploit the patients for financial gain, without regard for genuine patient care;

(ii) the Defendants engaged in illegal, collusive relationships in which the Pharmacy Defendants solicited and received illegal prescriptions from the Prescribing Defendants for the Fraudulent Pain Products in exchange for unlawful kickbacks and other financial incentives;

(iii) the Defendants submitted or caused to be submitted charges for the Fraudulent Pain Products pursuant to illegal, invalid, duplicitous and formulaic prescriptions; and

(v) the Pharmacy Defendants engaged in illegal bulk compounding by specializing in producing and dispensing large quantities of the Fraudulent Compounded Pain Creams in set formulations, in violation of Federal and New York State regulatory and licensing requirements imposed on drug manufacturers and outsourcing facilities, rendering it ineligible to receive reimbursement for No-Fault Benefits.

199. Accordingly, GEICO requests a judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, declaring that Direct Rx has no right to receive payment for any pending bills submitted to GEICO.

THE SECOND CLAIM FOR RELIEF
Against Yaguda and Yakutilov
(Violation of RICO, 18 U.S.C. § 1962(c))

200. GEICO incorporates, as though fully set forth herein, each and every allegation in the paragraphs set forth above.

201. Direct Rx is an ongoing "enterprise", as that term is defined in 18 U.S.C. § 1961(4), that engages in activities which affect interstate commerce.

202. Yaguda and Yakutilov knowingly have conducted and/or participated, directly or indirectly, in the conduct of Direct Rx's affairs through a pattern of racketeering activity consisting of repeated violations of the federal mail fraud statute, 18 U.S.C. § 1341, based upon the use of the United States mails to submit or cause to be submitted hundreds of fraudulent charges on a continuous basis for over five years, seeking payments that Direct Rx was not eligible to receive under the No-Fault Laws because: (i) the billed-for services were not medically necessary and/or the product of predetermined fraudulent protocols designed to exploit the patients for financial gain, without regard for genuine patient care; (ii) the Defendants participated in illegal, collusive relationships in which the Pharmacy Defendants solicited and received illegal prescriptions from the Prescribing Defendants for the Fraudulent Pain Products in exchange for unlawful kickbacks and other financial incentives; (iii) the billed-for services were the product of illegal, invalid, duplicitous and formulaic prescriptions; and (iv) Direct Rx engaged in illegal bulk compounding by specializing in producing and dispensing large quantities of the Fraudulent Compounded Pain Creams in set formulations, in violation of

Federal and New York State regulatory and licensing requirements rendering it ineligible to receive reimbursement for No-Fault Benefits. The chart attached hereto as Exhibit "1" sets forth the fraudulent claims that have been identified to-date which the Defendants submitted, or caused to be submitted, to GEICO through the United States mail and which comprise, in part, the pattern of racketeering activity identified through the date of this Complaint.

203. Direct Rx's business is racketeering activity, inasmuch as the enterprise exists for the purpose of submitting fraudulent charges to insurers. The predicate acts of mail fraud are the regular way in which Yaguda and Yakutilov operated Direct Rx, inasmuch as Direct Rx was never eligible to bill for or collect No-Fault Benefits, and acts of mail fraud therefore were essential in order for Direct Rx to function. Furthermore, the intricate planning required to carry out and conceal the predicate acts of mail fraud implies a threat of continued criminal activity, as does the fact that the Defendants continue to attempt collection on the fraudulent billing submitted through Direct Rx to the present day.

204. Direct Rx is engaged in inherently unlawful acts inasmuch as its very existence is an unlawful act, considering that it was created to exploit the New York "No-Fault" insurance system, engage in illegal, collusive arrangements involving medically unnecessary pain products, including compounded drugs, and bill pursuant to predetermined fraudulent protocols solely to financially enrich the Defendants. These inherently unlawful acts are taken by Direct Rx in pursuit of inherently unlawful goals – namely, the theft of money from GEICO and other insurers through fraudulent No-Fault billing.

205. GEICO has been injured in its business and property by reason of the above-described conduct in that it has paid approximately $548,369.00 pursuant to the fraudulent bills submitted by the Defendants Direct Rx.

206. By reason of its injury, GEICO is entitled to treble damages, costs, and reasonable attorneys' fees pursuant to 18 U.S.C. §1964(c), and any other relief the Court deems just and proper.

THE THIRD CLAIM FOR RELIEF
Against Yaguda, Yakutilov and the Prescribing Defendants
(Violation of RICO, 18 U.S.C. § 1962(d))

207. GEICO incorporates, as though fully set forth herein, each and every allegation in the paragraphs set forth above.

208. Direct Rx is an ongoing "enterprise", as that term is defined in 18 U.S.C. § 1961(4), that engages in activities which affect interstate commerce.

209. Yaguda, Yakutilov, and the Prescribing Defendants are employed by and/or associated with the Direct Rx enterprise.

210. Yaguda, Yakutilov, and the Prescribing Defendants knowingly have agreed, combined and conspired to conduct and/or participate, directly or indirectly, in the conduct of the Direct Rx enterprise's affairs, through a pattern of racketeering activity consisting of repeated violations of the federal mail fraud statute, 18 U.S.C. § 1341, based upon the use of the United States mail to submit or cause to be submitted hundreds of fraudulent charges on a continuous basis for over five years seeking payments that Direct Rx was not eligible to receive under the No-Fault Laws because: (i) the billed-for services were not medically necessary and/or were the product of predetermined fraudulent protocols designed to exploit the patients for financial gain, without regard for genuine patient care; (ii) the Defendants participated in illegal, collusive relationships in which the Pharmacy Defendants solicited and received illegal prescriptions from the Prescribing Defendants for the Fraudulent Pain Products in exchange for unlawful kickbacks and other financial incentives; (iii) the billed-for services were the product of illegal, invalid,

duplicitous, and formulaic prescriptions; and (iv) Direct Rx engaged in illegal bulk compounding by specializing in producing and dispensing large quantities of the Fraudulent Compounded Pain Creams in set formulations, in violation of Federal and New York State regulatory and licensing requirements rendering it ineligible to receive reimbursement for No-Fault Benefits. The chart attached hereto as Exhibit "1" sets forth the fraudulent claims that have been identified to-date which the Defendants submitted, or caused to be submitted, to GEICO through the United States mail and which comprise, in part, the pattern of racketeering activity identified through the date of this Complaint.

211. Yaguda, Yakutilov, and the Prescribing Defendants knew of, agreed to and acted in furtherance of the common and overall objective (i.e., to defraud GEICO and other insurers of money) by submitting or facilitating the submission of the fraudulent charges to GEICO.

212. GEICO has been injured in its business and property by reason of the above-described conduct in that it has paid approximately $548,369.00 pursuant to the fraudulent bills submitted by the Defendant Direct Rx.

213. By reason of its injury, GEICO is entitled to treble damages, costs, and reasonable attorneys' fees pursuant to 18 U.S.C. §1964(c), and any other relief the Court deems just and proper.

THE FOURTH CLAIM FOR RELIEF
Against Pharmacy Defendants
(Common Law Fraud)

214. GEICO incorporates, as though fully set forth herein, each and every allegation in the paragraphs set forth above.

215. Yaguda, Yakutilov, and Direct Rx intentionally and knowingly made false and fraudulent statements of material fact to GEICO and concealed material facts from GEICO in the

course of their submission of hundreds of fraudulent charges seeking payment for the Fraudulent Pain Products.

216. The false and fraudulent statements of material fact and acts of fraudulent concealment include: (i) in every claim, the representation that the billed-for services were medically necessary and properly billed when in fact the billed-for services were designed to exploit the patients for financial gain without regard for genuine patient care; (ii) in every claim, the representation that Direct Rx was acting in accordance with material licensing requirements and, therefore, eligible to receive No-Fault Benefits pursuant to Insurance Law § 5102(a)(1) and 11 N.Y.C.R.R. § 65-3.16(a)(12), when in fact the Defendants participated in illegal, collusive relationships in which the Pharmacy Defendants solicited and received illegal prescriptions from the Prescribing Defendants for the Fraudulent Pain Products in exchange for unlawful kickbacks and other financial incentives; (iii) in every claim, the representation that Direct Rx was acting in accordance with material licensing requirements and, therefore, eligible to receive No-Fault Benefits pursuant to Insurance Law § 5102(a)(1) and 11 N.Y.C.R.R. § 65-3.16(a)(12), when in fact the billed-for services were the product of illegal, invalid, duplicitous and formulaic prescriptions; and (iv) in every claim, the representation that Direct Rx was acting in accordance with materials licensing requirements and, therefore, eligible to receive No-Fault Benefits pursuant to Insurance Law § 5102(a)(1) and 11 N.Y.C.R.R. § 65-3.16(a)(12), when in fact Direct Rx engaged in illegal bulk compounding specializing in producing and dispensing large quantities of the Fraudulent Compounded Pain Creams in set formulations, in violation of Federal and New York State regulatory and licensing requirements.

217. Yaguda, Yakutilov, and Direct Rx intentionally made the above-described false and fraudulent statements and concealed material facts in a calculated effort to induce GEICO to pay charges submitted through Direct Rx that were not compensable under the No-Fault Laws.

218. GEICO has been injured in its business and property by reason of the above-described conduct in that it has paid approximately $548,369.00 pursuant to the fraudulent bills submitted, or caused to be submitted, by the Defendants through Direct Rx.

219. The Defendants' extensive fraudulent conduct demonstrates a high degree of moral turpitude and wanton dishonesty that entitles GEICO to recover punitive damages.

220. Accordingly, by virtue of the foregoing, GEICO is entitled to compensatory and punitive damages, together with interest and costs, and any other relief the Court deems just and proper.

THE FIFTH CLAIM FOR RELIEF
Against the Prescribing Defendants
(Aiding and Abetting Fraud)

221. GEICO incorporates, as though fully set forth herein, each and every allegation set forth above.

222. The Prescribing Defendants knowingly aided and abetted the fraudulent scheme that was perpetrated on GEICO by the Pharmacy Defendants.

223. The acts of the Prescribing Defendants in furtherance of the fraudulent scheme include knowingly purporting to prescribe the Fraudulent Pain Products, including the Fraudulent Compounded Pain Creams, and permitting their names to be used in the billing, prescription records and treatment reports submitted in support of the Fraudulent Pain Products despite their knowledge that Direct Rx was ineligible to bill for or to collect No-Fault Benefits in connection with the Fraudulent Pain Products because: (i) the Fraudulent Pain Products were not

medically necessary and/or were the product of predetermined fraudulent protocols designed to exploit the patients for financial gain without regard for genuine patient care; (ii) the Defendants participated in illegal, collusive relationships in which the Pharmacy Defendants solicited and received illegal prescriptions from the Prescribing Defendants for the Fraudulent Pain Products in exchange for unlawful kickbacks and other financial incentives; (iii) the Fraudulent Pain Products were the product of illegal, invalid, duplicitous and formulaic prescriptions; and (iv) Direct Rx engaged in illegal bulk compounding by specializing in producing and dispensing large quantities of the Fraudulent Compounded Pain Creams in set formulations, in violation of Federal and New York State regulatory and licensing requirements rendering it ineligible to receive reimbursement for No-Fault Benefits.

224. The conduct of the Prescribing Defendants in furtherance of the fraudulent scheme was intentional, significant and material. The conduct of the Prescribing Defendants was a necessary part of and was critical to the success of the fraudulent scheme because without their actions, there would be no opportunity for Direct Rx to obtain payment from GEICO and from other insurers.

225. The Prescribing Defendants aided and abetted the fraudulent scheme in a calculated effort to induce GEICO into paying charges to Direct Rx for medically unnecessary and illusory Fraudulent Pain Products that were not compensable under the No-Fault Laws, because they sought to continue profiting through the fraudulent scheme.

226. The conduct of the Prescribing Defendants caused GEICO to pay approximately $548,369.00 pursuant to the fraudulent bills that the Defendants submitted or caused to be submitted through Direct Rx.

227. The Defendants' extensive fraudulent conduct demonstrates a high degree of moral turpitude and wanton dishonesty that entitles GEICO to recover punitive damages.

228. Accordingly, by virtue of the foregoing, GEICO is entitled to compensatory and punitive damages, together with interest and costs, and any other relief the Court deems just and proper.

THE SIXTH CLAIM FOR RELIEF
Against Pharmacy Defendants
(Unjust Enrichment)

229. GEICO incorporates, as though fully set forth herein, each and every allegation in the paragraphs set forth above.

230. As set forth above, the Pharmacy Defendants have engaged in improper, unlawful, and/or unjust acts, all to the harm and detriment of GEICO.

231. When GEICO paid the bills and charges submitted by or on behalf of Direct Rx for No-Fault Benefits, it reasonably believed that it was legally obligated to make such payments based on the Defendants' improper, unlawful, and/or unjust acts.

232. Yaguda, Yakutilov and Direct Rx have been enriched at GEICO's expense by GEICO's payments, which constituted a benefit that Defendants voluntarily accepted and profited from, as a result of, among other things, the payments received and the receipt of kickback payments, notwithstanding their improper, unlawful, and unjust fraudulent billing scheme.

233. The Defendants' retention of GEICO's payments violates fundamental principles of justice, equity and good conscience.

234. By reason of the above, the Defendants have been unjustly enriched in an amount to be determined at trial, but in the approximate amount of $548,369.00.

JURY DEMAND

235. Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demands a trial by jury.

WHEREFORE, Plaintiffs Government Employees Insurance Company, GEICO Indemnity Company, GEICO General Insurance Company and GEICO Casualty Company demand that a judgment be entered in their favor and against the Defendants, as follows:

A. On the First Claim for Relief against the Pharmacy Defendants, a declaration pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, that the Pharmacy Defendants have no right to receive payment for any pending bills, amounting to approximately $1,590,338.00 submitted to GEICO;

B. On the Second Claim For Relief against Yaguda and Yakutilov, compensatory damages in favor of GEICO in an amount to be determined at trial but approximately $548,369.00, together with treble damages, punitive damages, costs, interest and such other and further relief as this Court deems just and proper;

C. On the Third Claim For Relief against Yaguda, Yakutilov, and the Prescribing Defendants, compensatory damages in favor of GEICO in an amount to be determined at trial but approximately $548,369.00, together with treble damages, punitive damages, costs, interest and such other and further relief as this Court deems just and proper;

D. On the Fourth Claim For Relief against the Pharmacy Defendants, compensatory damages in favor of GEICO in an amount to be determined at trial but approximately $548,369.00, together with punitive damages, costs, interest and such other and further relief as this Court deems just and proper;

E. On the Fifth Claim For Relief against the Prescribing Defendants, compensatory damages in favor of GEICO in an amount to be determined at trial but approximately $548,369.00, together with punitive damages, costs, interest and such other and further relief as this Court deems just and proper; and

F. On the Sixth Claim for Relief against the Pharmacy Defendants, a recovery in favor of GEICO in an amount to be determined at trial but approximately $548,369.00, together with punitive damages, costs, interest and such other and further relief as this Court deems just and proper.

Dated: Uniondale, New York
October 17, 2019

RIVKIN RADLER LLP

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